



**PERFORMANCE WORK STATEMENT  
ICF CONTRACT EP-C-11-005  
WORK ASSIGNMENT #1-01**

**Title:** Activities to support the development of revised Recreational Water Quality Criteria (RWQC)

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**Period of Performance:** January 1, 2012 through December 31, 2012

**LOE:** 3780 hours

**Contractor SOW:** 3.1, 3.4, 3.5, 3.6

**\*\*Note: No CBI data will be needed in the course of this work assignment.**

**Background:**

The mission of the United States Environmental Protection Agency's Office of Water (OW) under the Safe Drinking Water Act and the Clean Water Act (CWA) includes protecting the public health from adverse affects of microbial pollutants in waters for swimming.

A key component in the CWA framework for protecting and restoring waters for swimming is State adoption of Water Quality Standards (WQS) to protect swimmers from illnesses associated with "microbes" in the water. One of EPA's key roles is to recommend Recreational Water Quality Criteria (RWQC), under Section 304(a) of the CWA, for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water; in the 1960's the Federal government recommended a certain level of fecal coliform as the recreational criteria and in 1986 EPA recommended certain levels of enterococci and *E. coli* as its new recreational criteria. These organisms do not generally cause human illness themselves; rather, they

are merely indicators of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

It has been over 20 years since EPA last issued recreational criteria. Science - particularly molecular biology, virology and analytical chemistry - have advanced significantly during this time. EPA believes that new scientific and technical advances need to be considered, if feasible, in the development of new or revised 304(a) criteria. To this end, EPA has been conducting research and assessing relevant scientific and technical information to provide the scientific foundation for the development of new or revised criteria. The enactment of the BEACH Act provided EPA with an opportunity to conduct new studies and provided additional impetus to issue new or revised criteria for coastal recreational waters (specifically, for Great Lakes and coastal marine waters) to replace or amend the 1986 EPA recommended criteria. EPA believes that the new or revised criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection over the 1986 criteria.

**Quality Assurance:** Tasks 2-5 in this work assignment require the use of secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data or any other types of data used under this work assignment. The QAPP must be approved by the EPA before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

**Statement of Work:** The scope of work in this assignment will fall under the following task areas:

### **Task 1 – Workplan and Monthly Progress Reports**

The Contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The Contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must

include a table with the invoice LOE and costs' broken out by the tasks in this WA.

**Task 2 – Support ongoing Action Development Process Workgroup (ADP WG) efforts in the development of the Recreational Water Quality Criteria (RWQC)**

The Contractor shall assist in the ongoing efforts of the ADP WG. The Contractor shall attend weekly on-site ADP WG meetings, provide note-taking support, and submit meeting notes to the EPA WAM within two (2) business days of each ADP WG meeting. Additionally, the Contractor shall prepare meeting materials that may include, but are not limited to, presentations, briefing materials, hand-outs, and overviews.

*Travel:* Local travel is anticipated for this Task. No contractor travel outside of the Washington, D.C. metro area is required.

**Task 3 - Support for developing and editing the RWQC document and other related efforts**

*Task 3.1 Develop RWQC document*

This is a continuation of previous efforts to assist in the development of the RWQC document. This task will be an ongoing effort for the period of performance of this work assignment and a series of Drafts are expected. The most recent Draft RWQC document will be provided to the Contractor by the EPA WAM. The Contractor shall schedule a phone meeting with EPA WAM, within five (5) days of the receipt of the WA to discuss the schedule needs for the RWQC document.

*Task 3.2 Prepare briefing materials and other supporting documents pertaining to the RWQC document*

Briefing materials and other supporting documents will be needed during Final Agency Review, public comment, and during other parts of the Criteria development process. Briefing materials and supporting documents may include the development of secondary analyses to help support the development of the 2012 RWQC. The Contractor shall aid the in the development of any materials or presentations for these purposes.

*Task 3.3 Respond to Draft RWQC comments*

The Draft RWQC will undergo several types of reviews before it is finalized. These reviews include, but are not limited to, FAR, OMB review, public comment period, and interagency review. The Contractor shall respond to all comments from all reviews and provide an updated RWQC document to the EPA WAM.

While there are multiple ways to deal with the comments, EPA will likely choose either to use ICF's proprietary Comment Works or an Excel add-in. The decision regarding which of the two programs that EPA will choose for handling comments will be provided through technical direction.

### *Task 3.4 Prepare and submit Final RWQC document*

The Contractor shall prepare and submit a Final Recreational Water Quality Criteria (RWQC) document. This document will need to be 508 Compliant and formatted as directed by the EPA WAM.

*Travel:* No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

### **Task 4 – Gathering and preparing materials for the EPA docket**

A “docket” is a collection of documents made available by an agency for public viewing often associated with an opportunity for public comment. EPA’s dockets consist of materials used in developing a particular rulemaking or other action issued by the Agency.

#### *Task 4.1. Prepare comprehensive list of materials needed in the docket*

The Contractor shall help identify materials that need to be placed in the EPA docket. Docket materials may include, but are not limited to, publications, data, and meeting notes.

#### *Task 4.2. Gather and prepare materials needed in the docket*

Once the docket materials list has been reviewed by the EPA WAM, the Contractor shall help gather and prepare all the materials that need to be placed in the EPA docket. Again, docket materials may include, but are not limited to, publications, data, and meeting notes.

*Travel:* No contractor travel outside of the Washington, D.C. metro area is required is anticipated for this task.

### **Task 5 - General Project Support**

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractors may also be directed to participate in and/or conduct briefings. A weekly update call with the EPA WAM will be required for this work assignment, as needed.

Some meetings may require Contractor support and/or attendance for note-taking, presentations, and meeting preparation materials. Additionally, ODCs have been added for travel for up to two (2) trips. Details on travel dates and locations will be provided by the EPA WAM through technical direction, as further information becomes available.

*Travel:* Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

**SCHEDULE AND DELIVERABLES:**

Task No.	DELIVERABLE	Schedule
1	1.1 Work Plan	Within 15 calendar days of receipt of WA
2	2.0 ADP WG notes and other materials.	TBD
3	3.1 Draft RWQC	TBD
3	3.2 Supporting documents	TBD
	3.3 Draft RWQC - Response to comments	Within 1 week of the Review
3	3.4 Final RWQC	TBD
4	4.1 Comprehensive list of materials for EPA docket	TBD
4	4.2 Compilation of materials for EPA docket	TBD
5	5.0 General Project Support	TBD

**Knowledge and Skills Required:** Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology. The Contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

**General Requirements of the Work Assignment and Schedule:**

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

## **Attachment 1**

### **QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA**

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

#### **SECTION 1.0 PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES**

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, data analysis (i.e. statistical analysis & any other types of data analysis), and assumptions/recommendations based on the data analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

#### **SECTION 2.0 SOURCES OF SECONDARY DATA**

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

#### **SECTION 3.0 QUALITY OF SECONDARY DATA**

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)

- 3.2 The procedures for determining the quality of the secondary data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

#### **SECTION 4.0 DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION**

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).



EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-01

Other  Amendment Number:  
000001

Contract Number  
EP-C-11-005

Contract Period 01/01/2012 To 12/31/2012

Title of Work Assignment/SF Site Name

Base Option Period Number 1

REC WQ Criteria

Contractor  
ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.4, 3.5, 3.6

Purpose:  Work Assignment  Work Assignment Close-Out  
 Work Assignment Amendment  Incremental Funding  
 Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments:

The purpose of this amendment is to authorize three additional trips so that the contractor can continue to support Task 5. There are enough funds in the WA to cover the additional trips at no additional cost. Details on travel dates and locations will be provided by the EPA WAM through technical direction. All other Tasks (Task 1 - Task 4) remain unchanged.

Superfund

Accounting and Appropriations Data

Non-Superfund

SFO (Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2012 To 12/31/2012 Cost/Fee: LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name Sharon Nappier

Branch/Mail Code:

Phone Number 202-566-0740

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name

Branch/Mail Code:

Phone Number:

FAX Number:

(Signature)

(Date)

Contracting Official Name Cathy Basu

Branch/Mail Code:

Phone Number: 513-487-2042

FAX Number:

(Signature)

(Date)



**PERFORMANCE WORK STATEMENT  
ICF CONTRACT EP-C-11-005  
WORK ASSIGNMENT # 1-03**

**Title:** Incorporation of New Technologies to Support Criteria Development and Implementation

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**Period of Performance:** January 1, 2012 through December 31, 2012

**LOE:** 490 hours

**Contractor SOW:** 3.1, 3.3, 3.4, 3.6

**Background:**

An important goal of the Clean Water Act is to protect and restore waters for swimming. A key component in the CWA framework for protecting and restoring waters for swimming is State adoption of water Quality Standards (WQS) to protect swimmers from illnesses associated with "microbes" in the water. One of the EPA's key roles is to recommend recreational water quality criteria (under section 304(a) of the CWA) for adoption by the States. These EPA recommended criteria have been historically based on fecal matter in the water; in the 1960's the Federal Government recommended certain levels of fecal coliform as the recreational criteria and in 1986 EPA recommended certain enterococci and E. coli as its new recreational criteria.

To provide increased protection to swimmers, and for development of Total Maximum Daily Loads (TMDLs), National Pollutant Discharge Elimination System (NPDES) permitting requirements and water quality listings, EPA is now poised to revise its decade old ambient water quality criteria. The old criteria developed in 1986 was mainly based on enumerations of Fecal Indicator Bacteria (FIB) using culture-based methods, some of which were originally developed over a century ago. The advent of scientific methods particularly in the molecular measurements of diverse microbial populations, analytical chemistry, virology, genomics

including metagenomics warrant reevaluations of the 1986 criteria development process. Research advances have revealed many of the shortcomings and uncertainties associated with the 1986 water quality criteria. EPA is committed to develop new recreational water quality criteria for all water body types by 2012. Before new criteria can be developed, it is imperative that EPA undertakes critical research, analyze existing research data so that a scientifically defensible and health protective criteria can be adopted.

New molecular assays with intrinsic characteristics of high sensitivity, specificity, and reproducibility allow more direct enumeration of potential pathogens in recreational water. For example, Immunomagnetic Separation / Adenosine Triphosphate (IMS/ATP), TaqMan Protein Assays, fluorescent-based microbe detection assays allow enumerations of indicator organisms very reliably. EPA is contemplating inclusion of Quantitative Polymerase Chain reaction (qPCR) based enumerations of FIBs that can rapidly produce actionable results as opposed to the 24-48 hours that is now needed for culture based laboratory analysis. However, before new technologies can be incorporated in criteria development, numerous regulatory hurdles and related research needs must be met.

EPA anticipates a need to find out how we can use the data from the new technologies in the criteria development in the absence of epidemiological studies.

**Quality Assurance:** The tasks 2-3 in this performance work statement (PWS) require the use of primary/or secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data and other data collected to be used under this work assignment. The QAPP must be approved by the EPA before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

**Scope of Work:** The scope of the work in this PWS will fall under the following task areas:

#### **Task 1: Work plan and monthly progress reports**

The contractor shall develop a detail work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart, elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the EPA WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency. The plan should be submitted no later than 15 working days after receiving this work assignment.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

#### **Task 1.1 Develop project specific QAPP**

Tasks 2-3 and the new task 4 in this PWS require the use of primary and/or secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must create a project specific quality assurance project plan (QAPP) to assure the quality of the secondary data and other data collected under task 4 to be used under this work assignment. There is an existing project specific QAPP from WA # B-03 that covers tasks 2-3. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports and should follow Attachment 1 titled, QAPP Requirements for projects using secondary data.

The new task 4 in this work assignment requires an updated Quality Assurance Project Plan prior the commencement of work.

#### **Task 2: Develop methodology for incorporation of new methods without epidemiological studies**

In order to develop new robust Recreational Water Quality Criteria (RWQC), EPA is considering major technical methodologies that will allow future linkage to RWQC in the absence of additional epidemiological studies. EPA understands that the foremost requirements for RWQC include: RWQC should depend on the indicators that can be quantified reliably, robustly, and reproducibly; RWQC should protect individuals exposed to recreational waters; RWQC should protect children as they are more exposed and susceptible to pathogens; and RWQC should be scientifically defensible for application in a wide variety of geographical locations.

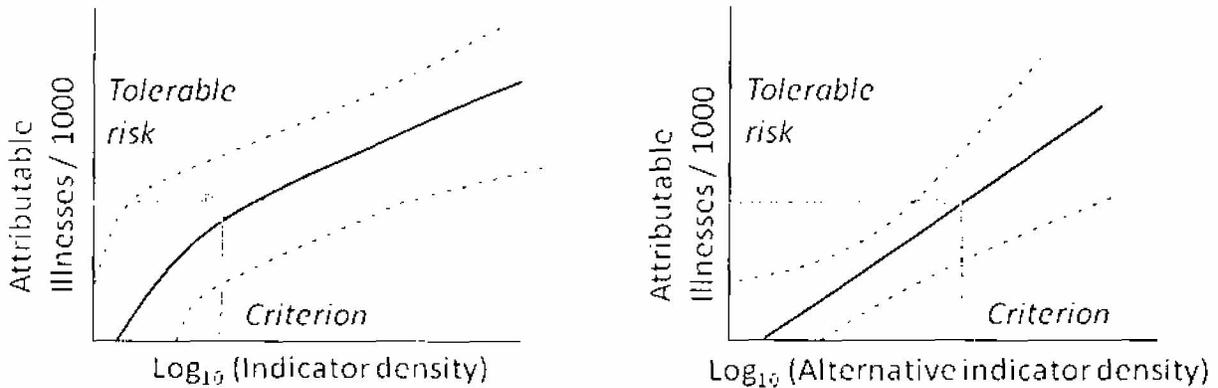
This PWS builds on previous work that is described in a report from a previous work assignment (WA 2-14, Task 2), under contract EP-C-07-036 titled *Options to Incorporate New Technologies and Methods into Recreational Water Quality Criteria without Additional Epidemiological Studies* (referred to as Report 2-14 hereafter).

The contractor shall further develop two approaches presented in Report 2-14, the risk level approach and the water quality approach. The below descriptions are from Report 2-14.

##### Risk Level Approach - Use of Non-Standard Indicators with Associated Health Effects Relationships

This approach, illustrated in Exhibit 1 below, involves relating two indicator-method combinations via selection of water quality standards from the two indicator-method combinations that relate to the same level of tolerable (acceptable/appropriate) risk. Although this approach allows for the use of established health effects relations for different indicators or from different epidemiological studies to be used within RWQC development, it requires that the health effects to which the indicators are related be the same and that the settings in which data

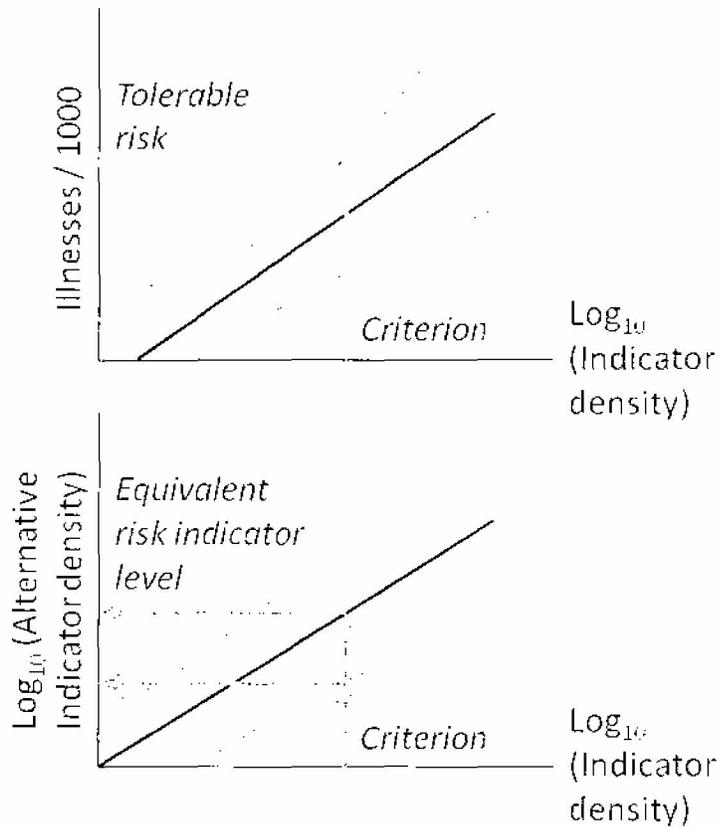
were collected be impacted by the same fecal pollution source. When epidemiological studies used to generate indicator density-health effects curves have different illness definitions (e.g., HCGI versus NEEAR GI), study designs, geographic regions, or time periods, analyses should be performed to convert the illness rates observed in the disparate studies to equivalent rates.



**Exhibit 1. Illustration of an Alternative Indicator with Health Effects Model Scenario.** In this approach the alternate indicator has acceptable health effects data. The same risk as applied in the RWQC is applied to the new indicator and its health effects data.

Water Quality Based Approach - Indicators that are Directly Related to “Standard” Indicators that are in Turn Related to Epidemiology Data

If RWQC are based on a particular indicator-method combination (referred to here as the “standard” indicator), an alternative indicator-method combination may be related to the health effects association via linkage of the alternative indicator to the standard indicator. For example, epidemiological studies have established an association between *Enterococcus* density as determined by qPCR and the incidence of GI illness. This health effects curve may be used to establish a qPCR *Enterococcus* water quality criterion that is protective of health at a chosen level of risk. The question “what *Enterococcus* density via membrane filtration provides the same health protection as the qPCR criterion?” may be answered as follows. A model relating culturable *Enterococcus* density to qPCR-measured *Enterococcus* can be established, and uncertainty in the model and conditions for which the model is valid may be defined. The model can then be used to determine the *Enterococcus* culture density equivalent to the *Enterococcus* qPCR RWQC. This process is illustrated in Exhibit 2 below.



**Exhibit 2. Linking to Health Effects Data via Equivalence of Water Quality Data**

For this method to be viable, a robust, verifiable relationship must be established between the standard and alternative indicator(s). Establishing this relationship requires: (1) selection of a “gold standard” method against which alternative methods are compared; (2) rigorous demonstration of a relationship between the standard and alternative indicator entailing demonstration that results of assays of environmental samples of the two indicators are consistently related (e.g., when one rises, the other also rises), recoveries of the methods are within an acceptable range, and uncertainty and variability of the alternative method is not significantly greater than that of the gold standard; and (3) establishment of the conditions/settings for which the relationship between the standard and alternative indicator is valid.

EPA is interested in methods that may be incorporated for water quality assessment in the future as well as those that may be adopted in the near term, including those that can possibly be incorporated into water quality standards in the absence of epidemiological studies.

**Identify methods and obtain datasets**

To test the feasibility of the two approaches outlined above, sample datasets will be compared using the two different approaches. The contractor shall discuss with the EPA WAM the selection of appropriate datasets for the methods listed in report 2-14. Promising methods that were listed include qPCR, Propidium Monoazida (PMA-qPCR), Reverse Transcriptase

Polymerase Chain Reaction (RT-PCR), IMS-ATP, Covalent (COV IMS-ATP), Transcriptase-mediated Amplification-Ribonucleic Acid (TMA-RNA), Nucleic Acid Sequence based Amplification (NASBA), microarray detection, and biosensors. The contractor shall include additional methods in the analysis if those methods have available datasets that allow comparison. The contractor shall not conduct literature searches to identify additional methods, but additional methods may come to the attention of EPA.

Appendix A of report 2-14 includes a table of sources of data for use in the risk level approach. Appendix B of report 2-14 includes a table of sources of data for use in the water quality based Approach. The contractor shall investigate whether data from these publications are appropriate for comparing with 2012 RWQC using the two approaches above. The criteria for determining appropriateness will be developed as part of task 2 of this work assignment. The EPA WAM will be involved in developing the criteria for determining appropriateness. It is expected that the form of the data in the publications may not be correct for the intended use in this work assignment. Therefore, if needed, the contractor in conjunction with the EPA WAM will seek raw data from authors where possible.

The contractor shall coordinate with the EPA WAM in the collection of datasets from various sources (e.g., Southern California Coastal Water Research Project (SCCWRP) and Water Environment Research Federation (WERF)).

Collection of datasets will be conducted such that the Office of Management and Budget (OMB) Information Collection Rule (ICR) will not be triggered.

### **Develop analysis plan and conduct analysis**

Completion of the analysis plan and analysis are dependent on contractor receiving draft proposed RWQC numeric values from EPA. Some datasets can be identified and obtained before draft proposed RWQC numeric values are available.

The contractor shall develop an analysis plan considering the obtained datasets and the two approaches. Upon EPA WAM approval, the contractor shall evaluate the two approaches to determine the robustness and relevance with respect to 2012 RWQC. The sample datasets for the new methods will be compared to sample datasets from methods used in the 2012 RWQC. Approved datasets will be provided by EPA and are likely to be from NEEAR studies and/or other studies using EPA approved methods. The contractor shall incorporate additional studies into the analysis if data are available.

### **Report findings**

The contractor shall submit a draft report of findings, including any recommendations for addressing potential “problem areas” in the analysis and potential use of the results in RWQC implementation. The contractor shall incorporate any additional analyses into revisions of the draft report upon receipt of additional datasets from EPA WAM.

EPA is interested in focusing on the performance of these methods to show that a common risk level can be applied resulting in a similar health protection standard for all CWA purposes. The two approaches should be developed such that there is clear statistical support for how the approaches can be used to link new methods/technology to 2012 RWQC implementation without undertaking any additional epidemiological studies.

It is of paramount importance that incorporation of the new methods/technology should result in equivalent health protection. EPA is interested in methods that may be incorporated for water quality assessment in the future as well as those that may be adopted in the near term, including those that can possibly be incorporated into water quality standards in the absence of epidemiological studies.

The report will include discussion of the strength of the statistical support for both approaches and possible limitations with the approaches.

Travel: Local travel is anticipated for this Task. No travel outside of the Washington, D.C. metro area is required.

### **Task 3: Multiple indicators measured together that result in combined risk: develop framework and collect and collate all the available information**

#### **This task is not under current budget**

In addition to the two approaches evaluated in Task 2, another approach outlined in report 2-14 is supported in this task.

#### Modeling Approach - Multiple Indicators Measured Together that Result in Combined Risk

Some water quality indicators may be related to fecal pollution sources but not to adverse health effects as measured in epidemiology studies. This approach for incorporating alternative methods into RWQC without conducting additional epidemiological studies is to use alternative data (e.g., physical conditions at a beach) to relate beach water quality to specific fecal pollution. Use of sanitary surveys, pilot monitoring programs, and modeling appears to be the best way to connect site conditions to fecal pollution sources. Models that might be used in this mode include QMRA and regression models, such as those used to develop the Nowcasting schemes in use at some Great Lakes beaches.

When multiple indicators (biological and non-biological) are used, estimated risks could be binned and action levels could relate to whether or not a group of measurements fell within a particular bin. For example, below certain levels of combined indicators, no public health concern would be expected. When a different number of risk factors are observed, then a tool box approach could be used to determine any actions that are required. Above even greater thresholds of combined indicators, more aggressive public health protection steps would be required, such as an immediate beach closure.

### **Identify, collect, and collate studies**

The contractor shall identify, collect, and collate the available studies/information related to indicators (biological and non-biological) used in beach modeling. These studies may be available in the published peer review literature, state-sponsored reports, EPA reports, and other Federal Agency reports (specifically USGS and USDA). The contractor shall coordinate with the EPA WAM as to the sources of these studies. The contractor shall search the following DIALOG databases: Biosis, NTIS, Enviroline, EMBASE, Water Resource Abstracts, Pascal, MedLine, FEDRIP, and Global Health. It is the goal of EPA to gather as many examples as possible to help inform the development of implementation policies and guidance related to 2012 RWQC. The contractor shall provide a bibliography for this task. It is EPA's concern that contractor shall include a list of references used for this task. In addition, contractor shall also include a list of unused references along with clear justification for not using them.

### **Summary of findings**

The contractor shall prepare a summary of the literature. This summary will not be a comprehensive literature review that describes each study and the implications of that study to RWQC. This summary will provide an overview of the types of data being used in current modeling projects and the extent to which similar data exist that could be incorporated into future modeling efforts.

### **Collated report**

The contractor shall collate the report from task 2 and the summary from task 3 into a combined report. The collated report will incorporate comments from the EPA WAM on the draft deliverables.

Travel: Local travel is anticipated for this Task. No travel outside of the Washington, D.C. metro area is required.

### **Task 4: Develop Technical Support Documents**

In order to develop Technical Support Documents for criteria implementation, EPA is anticipating detailed analyses of the Task 2 that shall be the basis of completing Task four. This work shall provide a tool for states to develop new methods or indicators for their water quality standards on a site-specific basis. Information on demonstrating the relationship between two-indicator method combinations shall be characterized under this task. The contractor shall be aware of the following time-line to generate the deliverable. The deliverable will go for internal/management review followed by the external peer review. Afterwards, the peer reviewed deliverable will again be evaluated by internal/management team.

Draft deliverable and Charge to Internal Reviewer (ORD/HECD)

- Response/Incorporation –
  - Management review -
  - Peer review contract -
  - Peer review package to ERG –
  - Final Peer Review Report -
  - Response to peer review comments --
- And incorporation of any changes to the deliverable (ICF)

After Peer Review

- Internal Review HECD -
- Management review -
- Final deliverable -

**Period of Performance/Milestones:** It is the Contractor’s responsibility to coordinate with EPA WAM while conducting these tasks.

Task	Milestone	Date due
1	Work Plan	Within 2 weeks of receipt of WA
1	1.1 QAPP	Within 3 weeks of receipt of WA
1	Kick-off meeting with EPA WAM	1 week after WP approval
2	Selection of new Indicators/Methods	1 week after WP approval
2	Collection of data sets from various sources in conjunction with EPA	1/2 month after WP approval
2	Develop analysis plan in conjunction with EPA, including EPA approval of plan	1 months after WP approval
2	Conduct Statistical analysis and compare method performance	1.5 months after WP approval
2	Submit draft report of initial findings	2.5 months after WP approval
2	Incorporate additional studies into analyses, if identified (Task 2)	Incorporate any additional analyses into revisions to draft report upon receipt from EPA
3	Identify, collect and collate available studies	TBD
3	Submit draft report of initial findings	TBD
3	Incorporate additional studies, if identified	TBD
4	Draft Report	3 months after WP approval
2&4	Revised Report	TBD

**Knowledge and Skills Required:** Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in statistical methods and have analysis and have advanced credentials in environmental microbiology. The contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques) water monitoring, applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

**General Requirements of the Work Assignment and Schedule:**

**Due Dates:** The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

**Delays:** The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

**Draft Documents:** The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

**Final Documents:** The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

**Final Documents:** The Contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the COR will provide appropriate technical direction.

**Final Peer Reviewed Document:** Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review. Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

## **Attachment 1**

### **QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA**

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

#### **SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES**

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

#### **SECTION 2.0 SOURCES OF SECONDARY DATA**

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

#### **SECTION 3.0 QUALITY OF SECONDARY DATA**

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)
- 3.2 The procedures for determining the quality of the secondary data shall be described.

- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

#### **SECTION 4.0 DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION**

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-03

Other  Amendment Number

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

Incorporation of New Technolog

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.4, 3.6

Purpose:

- Work Assignment
- Work Assignment Amendment
- Work Plan Approval
- Work Assignment Close-Out
- Incremental Funding

Period of Performance

From 01/01/2012 to 12/31/2012

Comments:

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and other such, shall be obtained by the EPA BC as needed and provided to the Contracting Officer. Work under conference related activities shall not occur until this approval.

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A

SFO (Max 2)

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 9)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period

01/01/2011 To 12/31/2012

Cost/Fee

LCE

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contract or WP Dated

01/17/2012

Cost/Fee

\$68,522.00

LCE: 490

Contractor Approved

Cost/Fee

\$68,522.00

LCE 490

Work Assignment Manager Name: Shumina Akter

(Signature)

(Date)

Branch/Mail Code

Phone Number: 202-566-1111

FAX Number:

Project Officer Name: Shirley Harrison

(Signature)

(Date)

Branch/Mail Code

Phone Number: 202-566-1111

FAX Number:

Other Agency Official Name: Shirley Harrison

(Signature)

(Date)

Branch/Mail Code

Phone Number: 202-566-1111

FAX Number:

Contracting Official Name: Sandra Stargardt-Lewis

(Signature)

(Date)

Branch/Mail Code

Phone Number: 202-566-1111

FAX Number:

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460 <b>Work Assignment</b>		Work Assignment Number 1-04 <input type="checkbox"/> Other <input type="checkbox"/> Amendment Number:								
Contract Number NP-C-11-005	Contract Period 01/01/2011 To 12/31/2012 Base                      Option Period Number 1	Title of Work Assignment/SF Site Name QMRA Activities								
Contractor ICF INCORPORATED, L.L.C.		Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6								
Purpose: <input checked="" type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Work Assignment Amendment <input type="checkbox"/> Incremental Funding <input type="checkbox"/> Work Plan Approval		Period of Performance From 01/01/2012 To 12/31/2012								
Comments										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data <input checked="" type="checkbox"/> Non-Superfund										
SH-C <input type="checkbox"/> (Max 2)                      Note: To report additional accounting and appropriations data use EPA Form 1900-69A.										
Line	ECN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period:		Cost/Fee:				LOE:				
01/01/2011 to 12/31/2012										
This Actor										
Total										
Work Plan / Cost Estimate Approvals										
Contractor W/P Dated		Cost/Fee:				LOE:				
Cumulative Approved:		Cost/Fee:				LOE:				
Work Assignment Manager Name John Ravenscroft						Branch/Mail Code:				
_____						Phone Number 202-566-1101				
(Signature)                      (Date)						FAX Number:				
Project Officer Name Shirley Harrison						Branch/Mail Code:				
_____						Phone Number: 202-566-1107				
(Signature)                      (Date)						FAX Number:				
Other Agency Official Name Shirley Harrison						Branch/Mail Code:				
_____						Phone Number: 202-566-1107				
(Signature)                      (Date)						FAX Number:				
Contracting Official Name Sandra Stargardt-Lewis						Branch/Mail Code:				
_____						Phone Number: 513-487-2006				
(Signature)                      (Date)						FAX Number:				

Work Assignment Form (Webforms v1.0)

 All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

SL

**Performance Work Statement  
ICF Contract # EP-C-11-005  
Work Assignment #1-04**

**Title:** QMRA Activities to Support Criteria Development and Implementation

**Work Assignment Manager:** John Ravenscroft (Mail Code 4304T)  
Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division  
1200 Pennsylvania Ave, N.W.  
Washington, DC 20460  
Phone (202) 566-1101  
E-mail: ravenscroft.john@epa.gov

**Alternate WAM:** Sharon Nappier (Mail Code 4304T)  
Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division  
1200 Pennsylvania Ave, N.W.  
Washington, DC 20460  
Telephone #: 202-566-0740  
E-mail: nappier.sharon@epa.gov

**Period of Performance:** Work Assignment Issuance through December 31, 2012

**\*\*Note:** No CBI data will be needed in the course of this work assignment.

Contractor PWS: 3.1, 3.3, 3.6

**Background:** EPA is on track to issue new CWA 304(a) Recreational Ambient Water Quality Criteria (AWQC) by December 2012. The science underpinning the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA would like to better understand the risks associated with other fecal sources and the potential wet weather impacts on surface waters. Quantitative Microbial Risk Assessment (QMRA) has been identified as a tool that the Agency can use to complement existing health data and to better understand the relative risks associated with non-human fecal sources of surface water contamination. The Agency's previously supported QMRA efforts have indicated that there are potentially significant differences in health risks associated between sources of fecal contamination and additional efforts are needed to better inform the regulatory framework. This work assignment covers various aspects of further development and application of QMRA in support of Recreational AWQC development and implementation.

**Task 1:** Work plan, monthly progress reports and quality assurance

### *Task 1.1: Work plan*

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

### *Task 1.2: Development of QMP and contract-level QAPP*

Work assignment-specific QAPPs were developed and approved under B-04, Task 1.3. The QMP and contract-level QAPP are still under development and additional effort is required to finalize both documents. Once approved, the contract-level QAPP will supersede the work assignment-specific QAPPs. The EPA WAM does not anticipate that substantial effort will be required for this task; however, the Contractor should budget for some minor efforts at the beginning of the year and low level effort for the remainder of the option year. The Contractor shall periodically review the QMP and QAPP with the EPA WAM to ensure continued applicability of these documents to ongoing efforts covered by the PWS of this contract.

### *Task 1.3: Information Quality Guidelines*

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. As directed by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

## **Task 2: General Project Support and Development of Technical Support Guidance**

EPA is planning to make available Quantitative Microbial Risk Assessment (QMRA) guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages. Task 2 comprises the different facets of the QMRA guidance project and includes project planning, communication strategies, and guidance document development.

*Task 2.1: Project planning and management*

The Contractor shall conduct project strategic planning in conjunction with the EPA WAM. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency timeline for publishing Recreational Ambient Water Quality Criteria (AWQC) and implementation guidance. The plan will also describe how each task will aid EPA in meeting its goals in relation to QMRA and the technical support guidance for implementation.

This task will require contractor travel to HQ for an initial planning meeting and quarterly update meetings thereafter during the period of performance of this work assignment. All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

The Contractor shall provide personnel knowledgeable in QMRA and also project planning and management for this process. Expertise in Microsoft Project (v. 2007) is preferred. The initial meeting is crucial to the entire overall work assignment and therefore will need to occur soon after the work assignment is received by the Contractor. Additionally, weekly update meetings between the EPA WAM and the Contractor shall be scheduled.

Deliverables under this subtask will include updating (as needed) the Gantt chart timeline listing all QMRA-related work with interim and final deliverable dates and quarterly project updates delineated. Given that the various QMRA tasks, both previously conducted by HECD and under the current effort, have been conducted incrementally, these pieces fit together to form a substantive body of work for the Agency. As part of the deliverables under this subtask, the Contractor shall include a discussion on the Agency's QMRA goals and objectives and how each of the tasks supports them. It is hoped that this exercise will also help to identify any gaps that will need to be addressed prior to the publication of the implementation guidance. Project milestones provided in this work assignment may be impacted by the results of this project planning. Any differences identified in these due dates will need to be identified and communicated via technical direction from the EPA WAM.

*Task 2.2: Project communication support:*

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project updates and other materials for internal and external audiences. These may include but are not limited to short briefing documents and PowerPoint

presentations. The contractors may also be directed to participate in and/or conduct briefings and meetings. The Contractor may also be directed to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The Contractor shall coordinate with the EPA WAM for the proper timing and need for these activities. A weekly update call with the EPA WAM will be required for this task, as needed. One specific part of this task is the “P4” communications paper that was started last year. The Contractor shall continue to coordinate updating this paper to reflect comments from EPA OW and ORD. This paper shall be included into the information used to develop the Technical Support Guidance (TSG) Volume B (see below).

A second major area under this task is Quantitative Microbial Risk Assessment (QMRA) outreach support. The Contractor shall assist EPA WAM with internal and external outreach to EPA management, both at Headquarters and with Regional offices, States, and other Stakeholder groups.

EPA needs to communicate its efforts to a broad audience. From engaging other scientists on technical issues to discussing regulatory actions with stakeholders and the public, EPA needs to be keenly aware of effective communication strategies. For all tasks under this work assignment, the Contractor shall discuss with the EPA WAM ways to achieve effective communication objectives. The audience for specific deliverables may be different even though the analytical approach may be similar. Questions to cover with the EPA WAM should address the audience and purpose of the deliverable, ideas for finding effective presentation strategies, suggestions for achieving the communication objectives given differing formats (e.g., written versus oral).

The Contractor may be requested to attend meetings of a scientific nature to present the results of the QMRA analyses to technical and non-technical audiences. Known at the time of submission of this work assignment is the following:

2012 Great Lakes Beach Association (GLBA) annual meeting. The information on the 2012 meeting is yet to be announced, but the GLBA consistently holds this meeting in the fall of the year. The Contractor shall engage with the EPA WAM to evaluate whether the 2012 meeting would be a good venue to help communicate the QMRA framework for site-specific criteria development. Consideration should be given to timing and meeting topic.

*Task 2.3: Development of QMRA Technical Support Guidance, QMRA framework:*

The purpose of this task is to continue development and to produce communication materials for the use of QMRA in the development of site-specific recreational water criteria intended as the basis for water quality standards (WQS). Past efforts by the Contractor have concentrated mainly on non-human sources, but the framework itself should be robust enough to consider other differences or site-specific characteristics.

The Contractor shall continue development of the Quantitative Microbial Risk Assessment (QMRA) framework for the purposes outlined above. This task shall build upon previous efforts conducted under B-04, Task 2.2 (QMRA guidance: how to conduct a QMRA for ambient waters, data needs and analytical approaches). The goal for this task will be to develop and to communicate the process by which QMRA can be used to derive alternative site-specific ambient water quality criteria for recreational use waters that will, in turn, be used to assemble a water quality standards (WQS) package. This deliverable is not the technical support guidance as detailed in other tasks below, but rather a description and discussion of the process and framework whereby QMRA could be used as a basis for a site-specific WQS package.

The deliverable shall address the way(s) a State can determine if any given site is a good candidate for the development of a site-specific water quality standards package based on a QMRA-derived criteria value. The Contractor shall include a discussion of the components of water quality standards package and how QMRA can assist in developing a site-specific water quality criteria value. To complete this part of the deliverable, the Contractor shall meet with the EPA WAM, WQS coordinators or other personnel in SHPD and the Regions. Logistics of these meetings may require the Contractor to attend meetings at EPA HQ. The Contractor shall address the differing approaches a State could use in running a QMRA (i.e., differing level of effort related to complexity of analysis).

The Contractor shall also consider the implications that the WQS package will be evaluated by EPA regional and headquarters personnel who will not necessarily have a technical background in microbiology, public health or risk assessment methodologies. Therefore, it will be **critical** that the Contractor consider the end-user audience as the deliverable is being developed. Technical material shall be transparently and sufficiently conveyed. The narrative shall be thoroughly developed and any graphical materials shall be explained completely. No assumption should be made that the audience will internalize figures or tables. These considerations are quite important as this material will be used to inform the policy decisions needed for QMRA to be used effectively. Much consideration should be given to the current paradigm in this area; end-users that are not familiar with risk assessment in general and hampered by misunderstandings related to the past and current technical bases for the nationally recommended recreational water quality criteria. It will be crucial that the Contractor develop effective communication and outreach materials if QMRA is to be applied effectively.

*Task 2.4: Development of QMRA Technical Support Guidance, Volume A:*

The purpose of this task is to develop a guide for use by States and localities for the purposes of deriving via the QMRA framework discussed in Task 2.3, site-specific criteria, notably for waters predominated by non-human sources of fecal contamination, for inclusion into WQS. This guide should also provide information to EPA Regions who are tasked to evaluate State WQS packages. Volume A of this guidance shall concentrate on how to determine if a water body is eligible for the development of site-specific criteria, what information can be used to provide a line of evidence approach for determining sources of fecal contamination (i.e., how to build a sanitary characterization), differing approaches to conducting a Quantitative Microbial Risk

Assessment (QMRA) (i.e., incorporate information from Task 2.3), the information needs for conducting a QMRA (at each level of effort), how to conduct a QMRA (i.e., how to build a transparent, clear, concise and reasonable risk assessment in support of public policy), deriving a site-specific water quality criterion, preparing a site-specific water quality standards package, and other topics as needed to be specified by the EPA WAM (and in consultation with HECD's partners in SHPD). The main goal for this deliverable is produce guidance for States to use in developing microbial Water Quality Standards (WQS) that are scientifically defensible, protective of the recreational designated use, and meet EPA standards for consideration and potential approval.

This task will require the Contractor to attend meetings with the EPA WAM and other staff at EPA Headquarters during the period of performance for the purposes of project updates, planning and communication. The Contractor shall anticipate travel to DC once per quarter for a total of 4 meetings at EPA HQ.

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

*Task 2.5: Development of QMRA Technical Support Guidance (TSG), Volume B:*

The deliverable under this task shall provide the end user a sufficiently detailed background on QMRA and the use of microbial risk assessment in developing site specific water quality standards. This volume shall provide the technical bases for the material in Volume A (Task 2.4). While this volume is purposefully technical in nature, it should still be produced in a manner that would be accessible to the end user.

The Contractor shall include the following topics in the scope of technical materials: assessing human health risks from fecal contamination in surface waters; use and application of epidemiology in development of water quality standards around the world; use of risk assessment to help interpret and extend observational studies; factors affecting occurrence, prevalence, fate and transport of pathogens and fecal indicator bacteria in surface waters; potential effects of management practices on sources of fecal contamination and implications to potential human health risks; and, other topics as specified by the EPA WAM.

*Task 2.6: Development of QMRA Technical Support Guidance (TSG), Volume C:*

The purpose of this task is to document a series of QMRAs conducted on recreational use waters. Each QMRA would be made available or peer reviewed/published separately. This volume will discuss each and give more information to explain how each risk assessment fits into context with the materials in volumes A and B. The context that will need to be developed will consist of a compare and contrast discussion with EPA recommended ambient water

quality criteria for recreational waters and other risk assessments. The Quantitative Microbial Risk Assessments (QMRAs) can be discussed as ‘case studies’.

At present, the EPA WAM envisions this “volume” to comprise a report and will reference the risk assessments discussed and where to find them (should copyrights allow, those assessments can be included as appendices). Existing material for inclusion in this volume includes: Ohio case study; Boqueron case study, Chicago Area Waterways (CAWS) case study, and Southern California Coastal Water Research Project (SCCWRP) case study. However, the SCCWRP case study may not occur due to tightening budgets and lack of EPA resources. The Contractor shall coordinate with the EPA WAM early and often to better scope out other potential material for this volume.

An urgent deliverable (see milestone table) will be needed under this task within 2 weeks of receiving the work assignment. The Contractor shall, in conjunction with the EPA WAM, develop a cost estimate for pathogen (and Fecal Indicator Bacteria (FIB)) monitoring consistent with SCCWRP’s study design for their case study QMRA project. The estimate will detail the resources needed to monitor for the microbes (FIB, pathogens, and Microbial Source Tracking (MST) markers). Data generated from such an estimate should be directly usable in conducting a QMRA in support of developing a site-specific water quality criterion.

The Contractor may be required to attend meetings with SCCWRP to discuss planning, scoping, conduct, or analyses associated with the case study project. As mentioned before, all appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

### **Task 3: QMRA anchoring**

#### *Task 3.1: Marine National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) studies*

A draft report was submitted by the Contractor on 11/30/11. The Contractor shall update the draft to reflect EPA comments. The results of this effort will be included in the TSG Volume B. The Contractor shall discuss with the EPA WAM the benefit of having the results peer reviewed by a scientific journal or as part of Volume B (and peer reviewed separately). Once updated (as discussed below), the Contractor shall also submit as part of the revised draft a project summary aimed at a non-technical audience. The summary should provide the important conclusions to be drawn from the analysis along with a discussion of how these results fit into context with the existing knowledgebase (not necessarily restricted to the area of QMRA).

The Contractor shall update the analysis of the QMRA anchoring report for the Surfside epidemiology study with the available sanitary characterization information. The source of fecal contamination affecting the Surfside study area was determined to be non-human. Based on

the observed source(s), as documented in OST's sanitary survey report, this Quantitative Microbial Risk Assessment (QMRA) should mirror previous efforts where non-human agricultural fecal sources were characterized.

As stated in the draft report, the results of the sanitary survey for Surfside beach, the available water quality data from the Surfside epidemiology study, a literature review on fecal indicator and pathogen densities in the relevant fecal contamination source for Surfside beach, and the previously developed QMRA methods should be integrated to update the draft analysis.

### *Task 3.2: Marion et al. study*

A draft report was submitted in a memorandum by the Contractor in July 2011. EPA WAM provided comments on this memorandum. Additionally, EPA WAM, the Contractor and Ohio State University (OSU) staff met to discuss the QMRA and ways to improve the report for a final version that could be submitted for peer review. Dr. Jiyoung Lee of OSU shared additional data with EPA that should be considered in a revised QMRA. The Contractor shall continue to coordinate with EPA WAM and OSU in order to update the QMRA with additional information and/or analyses as identified in previous comments. The additional information includes, but not limited to: onset to illness data for swimmers; rainfall dates, including Army Core of Engineers gauge data and lake inflow data; and, additional monitoring data as appropriate (e.g., culture and Quantitative Polymerase Chain Reaction (qPCR) data for FIB, adenovirus occurrence, etc.). An updated report suitable for internal management review shall be submitted to EPA WAM within two weeks of the workplan approval. Comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be submitted to EPA WAM by the end of March 2012.

This collaboration provides an excellent opportunity for the EPA to engage with external researchers. The Contractor shall assist in maintaining the good relationship EPA has established with the OSU staff. Any ideas for improving this collaboration will be quite welcome to the EPA WAM. Additionally, the contractor may be requested to provide facilitation assistance with the OSU group in order to maintain sufficient progress towards peer reviewing the QMRA schedule (see milestone table).

### *Task 3.3: Boqueron*

The Contractor submitted a draft report on 11/11/11. The Contractor shall update the draft to reflect EPA comments. The Contractor shall submit an updated draft report, of sufficient quality for internal management review, within 1 month of receiving EPA comments. Any comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be submitted to EPA by the end of April 2012.

The Contractor shall provide assistance to the EPA WAM in developing communication materials aimed at non-technical and technical audience. EPA WAM will be discussing the results of the Boqueron QMRA and monitoring study with stakeholders in Puerto Rico in

February 2012. The Contractor shall engage the EPA WAM within 2 weeks of receiving the work assignment to discuss the content and organization of these materials.

*Task 3.4: QMRA anchoring communication support*

The Contractor shall develop communication materials for each of the task 3 QMRA reports aimed at non-technical, policy-oriented audiences (see milestone table). Materials aimed at the general population may also be needed and shall be prepared by the contractor when technical direction is received. The Contractor shall discuss the importance of the findings of the Task 3 efforts, how they fit into context with other QMRA and other results, and any science or policy implications. Other topics to be included in these materials will be discussed as needed with the Contractor.

Additionally, the Contractor may be required to attend one or two planning meetings at EPA Headquarters to present results to management and staff. Timing for the meeting(s) has not been finalized at the time of the submission of this work assignment; however, ODCs for two visits to EPA Headquarters are included.

**Task 4: Relative QMRA refinement**

*Task 4.1: Evaluating source and receptor locations*

This task shall continue support for efforts begun under B-04. The contractor shall meet with the EPA WAM to develop a list of modeling needs (e.g., FRAMES-related) to support implementation of QMRA. The contractor shall also coordinate with the EPA WAM to discuss with other EPA personnel about advancements in dose response modeling (e.g., animal studies translated to human health estimates). This discussion should evaluate whether these advancements could be incorporated into the Microbial Risk Assessment Information Tool (MRA-IT) and then tailored to the FRAMES QMRA approach.

The contractor shall continue to discuss with the EPA WAM and ORD-Athens personnel the current capabilities for fate and transport modeling in the context using the QMRA framework for deriving water quality standards. HECD will need to have these discussions documented for use with communication with management.

*Task 4.2: Relative QMRA refinement: QMRA analysis of mixed fecal sources*

The Contractor submitted a draft memo discussing the analytical approach for conducting a QMRA evaluating human health risks from exposure to water impacted by mixed sources of fecal contamination (i.e., human and non-human FIB sources, human and non-human pathogen sources, and animal and non-fecal FIB sources) under B-04.

The Contractor shall update the draft memo incorporating EPA comments. An updated report suitable for internal management review shall be submitted to the EPA WAM within two weeks of the receiving EPA comments. Comments from this review shall be discussed with the EPA WAM and the report revised accordingly. A final report suitable for peer review shall be

submitted to the EPA WAM within two weeks of receiving comments from the management review.

#### **Task 5: Primary and Secondary Contact evaluations**

The purpose of this task is to evaluate health risks associated with different water-based activities performed in the US. This task will be part of the scientific basis for policy measures to place activities into appropriately protective recreational use categories (e.g. primary contact recreation, secondary contact recreation), and to determine the level of water quality necessary to protect individuals engaging in each of these activities.

The Contractor submitted a draft Quantitative Microbial Risk Assessment (QMRA) report during the base year under this task. For this work assignment, the Contractor may be asked to provide responses to questions from EPA WAM on the analysis and conclusions contained in the deliverable. The Contractor should consider this task 'low level of effort' for purposes of developing the workplan.

#### **Task 6: Children's Health, Sensitive Subpopulations, Alternate Study designs, and Environmental Justice evaluations**

##### *Task 6.1: QMRA approaches to evaluate risks to sensitive subpopulations and children's health.*

The Contractor submitted a draft deliverable in the base year under this task. This task is being removed from this work assignment and included with 1-07 since that work assignment specifically addressed children's health, sensitive subpopulations and environmental justice issues.

##### *Task 6.2: Alternate epidemiology study designs*

EPA is interested in comparing results from epidemiology studies conducted with alternative study designs. The Agency has conducted past efforts in this area to identify appropriate data sets and design an analytical approach for that data. The Contractor shall build upon those past efforts and secure data from an RCT (randomized control trial) epidemiology study sufficient for a comparative analysis with a PC (prospective cohort) design. The Contractor shall conduct the following activities:

Coordinate with the investigators on an RCT study to obtain the raw data from that study and re-analyze the results using the statistical methods employed by Wade and colleagues for the EPA epidemiology studies. This analysis will provide an indication of whether or not results from RCTs and PCs can be compared directly and will help to answer the question of whether the differences observed in existing epidemiology studies are due to the study design or other factors.

Use a QMRA framework to translate results from an RCT to one that is comparable to a PC study. Conduct sensitivity analyses to identify the model parameters that most strongly

influence the results. Compare the results with those from #1. The contractor shall report findings to EPA WAM in a memorandum, including potential next steps for this analysis.

Efforts conducted in the base year resulted in the identification of potential datasets for this analysis. However, there has been reluctance from external researchers to share the data needed for this comparison. This subtask is included here to maintain the potential for this analysis in the option year, but the Contractor should consider this subtask as a placeholder and low priority. Should data become available, the Contractor shall discuss the path forward with the EPA WAM before any LOE is expended on this task.

#### **Task 7: Chicago Area Waterways (CAWS) QMRA**

The goal of this task is to develop a QMRA-based evaluation of human health risks from exposure to the Chicago Area Waterways. This evaluation should consider the range of exposures covered by the traditional metrics of primary and secondary contact recreation. The QMRA analysis and characterization include and build upon previous work under B-04 Task 5. The Agency previously provided comment on both the CAWS QMRA conducted by the Metropolitan Water Reclamation District of Greater Chicago (MWRDGC) and the Chicago Health Environmental Exposure and Recreation Study (CHEERS) epidemiology study led by Sam Dorovitch of U. of Illinois at Chicago. Both studies suffer from design constraints and the Agency is unsure how to properly interpret the results.

The Contractor submitted a draft QMRA using both literature-reported values for pathogens in secondary treated, but non-disinfected effluent and the results from pathogen monitoring on the CAWS. The EPA WAM sent comments on this draft on December 21, 2011. These comments will need to be addressed in the next version of the report (see milestone table).

The Contractor shall evaluate the following points and questions in the revised QMRA (this list is not exhaustive and other points/questions/comments may arise from the technical discussion between ICF and EPA):

- Estimate illness from “primary” and “secondary” exposure to treated POTW effluent (e.g., ‘end of pipe’ exposure to secondary treated effluent with and without disinfection). Also, conduct the same analysis for exposure to CSO-impacted waters. This analysis must be accompanied by a thorough discussion, including non-technical presentations of data, analysis, and results. The discussion should cover potential implications for interpreting the RWQC.
  - Use literature values for human sewage for pathogens and FIB.
  - Use literature values for treatment efficacy on both groups of microbes; include chlorination and UV.
  - Incorporate fate and transport information.
  - Address the following questions:
    - Given the epidemiological relationships observed at POTW-impacted beaches and how those relationships inform the level of protection for the recommended RWQC, what is the expected

level of protection at the end of pipe? Conversely, what would be an equally protective criteria at the POTW compared to the beach? (address these questions in terms of FIB – culture and molecular-based enumerations – and with pathogens like norovirus (reference) or enteroviruses in general)

- Compare this analysis with analyses based on the CAWS data.
  - Are available microbial data reflective of the prevailing wet and dry conditions within the CAWs. Was the existing pathogen monitoring sufficient? Were sampling locations sufficient to represent the conditions expected to occur (e.g., wet weather and CSO events)?
- How do the estimated probabilities of illness compare to the observational results from the CHEERS epi study? What can be said about the other illness endpoints that seemed important from the epi study results (e.g., AFRI, eye, etc.)? Would those alternative endpoints be affected by disinfection (i.e., while the draft report addressed the effect of disinfection on GI illness, would not the effect actually be more pronounced as can be seen in the CHEERS study)?
- Include estimates of illness for primary contact activities and include analyses and discussion that compares and contrasts the differences for high, middle and low ingestion activities. Can a similar approach to binning these activities as was discussed with B-04 task 5 be taken here?
- Include the relative QMRA step. What does the illness estimate translate into in terms of FIB? Relate this to potential primary and secondary contact WQS for the CAWs.
- Can one derive a secondary contact recreational water quality criteria based on the QMRA framework utilized in this exercise? (If so, how? Discuss.)
- Does using a probabilistic analysis increase confidence in the estimated probabilities of illness compared to the static analysis?

There is considerable interest within EPA, both at HQ and in Region 5, in this particular QMRA. While this is not a final expectation, the Contractor may be requested to visit Region 5 in order to discuss other potential analyses. This visit is not definite, but ODCs have been included in case the need for the meeting materializes.

The Contractor shall revise the draft as a risk assessment for informing policy decisions. While it is fine to use the MRA tools document as a starting guide, the Contractor shall be mindful that EPA has a long history of using risk assessments in support of decision making, so this QMRA should reflect existing Agency guidance on risk assessment.

The Contractor shall submit technical and non-technical briefing materials along with the revised assessment. These materials may be a “two-pager” and/or a slide presentation and will be discussed during the weekly meeting.

## **General Requirements of the Work Assignment and Schedule:**

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
<b>Task 1: Work plan, monthly progress reports and quality assurance</b>		
Workplan	1.1	Within 15 calendar days of receipt of work assignment
Development of QAPP and QMP	1.2	Within 15 calendar days of receipt of work assignment
Information Quality Guidelines	1.3	Discuss with EAP WAM within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
<hr/>		
<b>Task 2: General Project Support</b>		
Project Planning and Management	2.1	Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Meeting shall update project Gantt chart, goals and objectives statement, and gap analysis due within 2 weeks of initial meeting. Drafts of this deliverable would be expected at the close of the initial meeting. Subsequent meetings to be held roughly every quarter thereafter.
Project Communications Support	2.2	After the workplan approval, throughout the period of performance. See meeting dates in WA text. Other communication materials will be dependent on the analytical results. Revisions to the P4 paper due within 2 weeks of receiving comments from OW and ORD.
QMRA TSG: QMRA Framework	2.3	Draft for internal review, 3/15/12 (communication materials included); Final by 4/30/12 contingent on EPA comments.
QMRA TSG: Vol A	2.4	Draft for internal review: By 5/16/12; Draft for peer review, 6/19/12; Draft final by 10/31/12; Final by 11/28/12
QMRA TSG: Vol B	2.5	Draft for internal review, by 10/16/12; draft for peer review by 11/27/12; <i>Draft final</i> by 3/29/13; <i>Final</i> by 5/30/13

QMRA TSG: Vol C	2.6	Vol C mainly consists of reports prepared individually under other tasks - refer to those tasks for component schedules. For supplemental text expanding on those reports: Ohio, Boqueron and CAWS case study text (draft by 8/15/12; final within 2 weeks of receiving EPA comments). Develop cost estimate for reference pathogen testing using SCCWRP study design, within 2 weeks of receiving work assignment.
<b>Task 3: QMRA Anchoring</b>		
Marine NEEAR reverse QMRA	3.1	Updated draft within 1 month of receiving EPA comments. Discuss incorporation of results into TSG Vol B and venue for peer review and publication at weekly WA meeting at weekly meeting.
Marion anchoring QMRA	3.2	Update draft report based on EPA and OSU comments and other analyses, with 2 weeks of workplan approval. Updated draft will be reviewed by HECD management. Mgmt comments will be addressed and final report to be submitted for peer review by end of March, 2012.
Boqueron QMRA	3.3	Updated draft within 1 month of receiving EPA comments. Updated draft will be reviewed by HECD mgmt. Mgmt comments will be addressed and final report to be submitted for peer review by end of April, 2012.
QMRA Communications Support	3.4	Non-technical, policy oriented communication materials, within 1 month of workplan approval. Materials for general audiences due date to be determined by technical direction. Meeting and presentation at EPA HQ to be determined.
<b>Task 4: Relative QMRA refinement</b>		

Evaluating sources and receptor locations	4.1	Ongoing throughout the period of performance. Periodic teleconference calls (e.g., bimonthly) with HECD, ICF, and ORD-Athens. Deliverables for this task include notes of teleconference meetings and synopses of modeling developments and capabilities used for internal communication.
Refinement of QMRA analyses of mixed fecal sources	4.2	Updated draft within 2 weeks of receiving EPA comments. Updated draft will be reviewed by HECD mgmt. Mgmt comments will be addressed and final report to be submitted for peer review 2 weeks after receiving EPA management comments.
<b>Task 5: Primary and Secondary Contact</b>		
Communications support		Low LOE effort; as needed throughout the period of performance.
<b>Task 6: Sensitive Subpopulations and alternate study designs</b>		
Sensitive subpops and children's health	6.1	Moved to 1-07
Alternative epidemiology study design	6.2	Low LOE effort; continue efforts to identify RCT data sets.
<b>Task 7: CAWS QMRA support</b>		
Update draft QMRA addressing EPA comments and inclusion of additional questions/information.	7.1	Updated draft within 1 month of workplan approval. Progress to be discussed at weekly meetings with WAM. Updates shall be reflective of EPA comments, and the draft shall include and fully discuss the necessary context information and be aimed at the appropriate audience.
Produce communication materials for non-technical audience	7.2	Submitted with updated draft. Content and format to be discussed at weekly WA meetings.
Include probabilistic parameters and analysis to updated risk assessment and identification and inclusion of Region 5-specific questions/concerns.	7.3	Refinement of revised draft (7.1) upon receiving EPA comments and planning discussion with EPA WAM. Discussion due within 15 days of receiving EPA comments, QMRA refinements due within 1 month of receiving EPA comments.

## Attachment 1

### QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

#### SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that -key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

#### SECTION 2.0, SOURCES OF SECONDARY DATA

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

#### SECTION 3.0, QUALITY OF SECONDARY DATA

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if

applicable. (If appropriate, a related QAPP containing this information can be referenced.)

3.2 The procedures for determining the quality of the secondary data shall be described.

3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

#### SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.

4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.

4.3 The expected product document that will be prepared shall be specified (e.g., journal article, final report, etc.).

## Attachment 2

### QAPP Requirements for Research Model Development and Application Projects

**GENERAL REQUIREMENTS:** Include cover page, distribution list, approvals, and page numbers.

#### **0. COVER PAGE (MODEL DEVELOPMENT AND MODEL APPLICATION)**

Include the Division/Branch, project title, revision number, EPA technical lead, QA category, organization responsible for QAPP preparation, and date.

#### **1. PROJECT DESCRIPTION AND OBJECTIVES (MODEL DEVELOPMENT AND MODEL APPLICATION)**

*In this document, "project" can mean (a) development or substantial modification of a model for application to address a general problem; (b) application of an existing model (including minor modification to the existing model) to address a specific problem; or (c) a development or substantial modification and application of a model to address a specific problem.*

- 1.1 State the purpose of the project and list the project objective(s). Indicate whether a new model will be developed or an existing model will be used.
- 1.2 Describe the problem, the data to be generated by the model, how the data will be used to address the problem, and the intended users of the data. Describe the environmental system/setting to be modeled, where the model will be applied, and the circumstances and scenarios to be considered for the modeled system.

#### **2. ORGANIZATION AND RESPONSIBILITIES (MODEL DEVELOPMENT AND MODEL APPLICATION)**

- 2.1 Identify all project personnel, including QA, and related responsibilities for each participating organization, as well as their relationship to other project participants.
- 2.2 Include a project schedule that includes key milestones.

#### **3. MODEL SELECTION (MODEL APPLICATION ONLY)**

- 3.1 Discuss model selection with respect to how it will be used and how it is consistent with the project objectives. Include fundamental details such as whether the model will be used to predict the world beyond the model or in scenario analysis of the model itself. Describe the limits to where the model is applicable.
- 3.2 Provide a description of the model attributes/capabilities required for the project. This description should include hardware requirements and restrictions. Provide an overview of the candidate model attributes, including:

- model origin and its original purpose, if applicable
  - model structure (e.g., stochastic vs. deterministic, structural framework)
  - parameters and variables
  - the algorithms and equations that have been developed to support the model theory, along with the sources of the algorithms
  - spatial extent (individual, group, population)
  - spatial resolution (location independent/dependent, dimensionality)
  - temporal extent (length of modeling period)
  - temporal resolution (time step)
- 3.3 Identify the model to be used or, if the model has not yet been selected, describe the process to be used for the selection of an existing model.
- 3.4 Identify specific requirements for application of the selected model for this specific purpose (e.g., current and appropriate data, parameter values, assumptions).

#### **4. MODEL DESIGN (MODEL DEVELOPMENT ONLY)**

- 4.1 Describe the conceptual model(s) for the system, including model parameters.
- 4.2 Identify algorithms and equations that have been developed to support the model theory, or if such equations are not already available, describe the process used to develop these equations.
- 4.3 Specify required sources for model databases and any requirements for these data (e.g., quality, quantity, spatial, and temporal applicability). If data sources are not currently known, describe the criteria used to identify sources. Describe how any data gaps will be filled.

#### **5. MODEL CODING (MODEL DEVELOPMENT ONLY)**

- 5.1 Discuss the requirements for model code development, where applicable.
- 5.2 Identify computer hardware and software requirements.
- 5.3 Discuss requirements for code verification.

#### **6. MODEL CALIBRATION (MODEL DEVELOPMENT AND MODEL APPLICATION)**

*Calibration is the process of adjusting model parameters within physically defensible ranges until the resulting predictions give the best possible or desired degree of fit to the observed data. Calibration should be applied each time the model is modified.*

- 6.1 Discuss how the model will be calibrated.
- 6.2 Identify the type and source of data (e.g., new data, existing data, professional judgment, expert opinion elicitation) that will be used to calibrate the model, including any requirements for the data (quality, quantity, and spatial and temporal applicability). If data sources are not currently known, describe the criteria used to identify sources.
- 6.3 Specify acceptance criteria which need to be met for the difference between

predicted and observed data during model calibration, where applicable. The statistical methods (e.g., goodness-of-fit, regression analyses) or expert judgment to be used should also be discussed.

**7. MODEL VERIFICATION (MODEL DEVELOPMENT AND MODEL APPLICATION)**

*Verification consists of comparing the predictions of a calibrated model with available data that were not used in the model development and calibration.*

- 7.1 Discuss the approach to be used for model verification. Describe how the verification is appropriate based on the model's purpose. Identify the type and source of data (e.g., new data, existing data, synthetic test data sets, professional judgment, expert opinion elicitation) that will be used to verify the model. If data sources are not currently known, describe the criteria used to identify sources.
- 7.2 Discuss the characterization of model uncertainty (model framework, model input, and model applicability) and sensitivity (model application only).
- 7.3 Describe any requirements (quality, quantity, and spatial and temporal applicability) for the data that will be used to verify the model.
- 7.4 Describe the approach used to determine if the independent data verify the model predictions. Specify the criteria which need to be met for the difference between predicted and observed data for the model to be considered to be verified. Discuss any statistical methods to be used (e.g., goodness-of-fit, regression analyses).

**8. MODEL EVALUATION (MODEL DEVELOPMENT AND MODEL APPLICATION)**

- 8.1 List and describe the qualitative or quantitative assessment process to be used to generate information to determine whether a model and its analytical results are of a quality sufficient for the intended use.
- 8.2 List and describe any independent/external evaluation and review of the model and model design, such as scientific peer review.

**9. MODEL DOCUMENTATION (MODEL DEVELOPMENT AND MODEL APPLICATION)**

Specify the requirements for model documentation. Good documentation includes:

- final model description, final model specifications (model development only), hardware and software requirements, including programming language, model portability, memory requirements, required hardware/software for application, data standards for information storage and retrieval
- the equations on which the model is based (model development only)
- the underlying assumptions
- flow charts (model development only)

- description of routines (model development only)
- data base description
- source code (model development only)
- error messages (model development only)
- parameter values and sources
- restrictions on model application, including assumptions, parameter values and sources, boundary and initial conditions, validation/calibration of the model, output and interpretation of model runs (model development only)
- the boundary conditions used in the model
- limiting conditions on model applications, detail where the model is or is not suited
- changes and verification of changes made in code
- actual input data (type and format) used
- overview of the immediate (non-manipulated or -post processed) results of the model runs (model application only)
- output of model runs and interpretation
- user's guide (electronic or paper)
- instructions for preparing data files (model development only)
- example problems complete with input and output
- programmer's instructions
- computer operator's instructions
- a report of the model calibration, validation, and evaluation (model development only)
- documentation of significant changes to the model
- procedures for maintenance and user support, if applicable

## **10. REPORTING (MODEL DEVELOPMENT AND MODEL APPLICATION)**

- 10.1 List and describe the deliverables expected from each project participant.
- 10.2 Specify the expected final product(s) that will be prepared for the project (e.g., journal article, final report).

## **11. REFERENCES**

Provide the references either in the body of the text as footnotes or in a separate section.

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-04

Other  Amendment Number:

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

QMRA Activities to Support Ori

Contractor

ICM INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.6

Purpose:

- Work Assignment
- Work Assignment: Close-Out
- Work Assignment Amendment
- Incremental Funding
- Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments

This workplan will be incrementally funded. The contractor shall not exceed the ceiling limit of \$138,656. The contractor shall notify the EPA WAX prior to reaching ceiling limit. As additional funding becomes available, this workplan will be fully funded.

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 7900-69A.

SFC (Max 2)

LINE	DCN (Max 6)	Budget FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012 Cost/Fee: \$0.00 LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 03/12/2012 Cost/Fee: \$256,586.00 LOE: 1,698

Cumulative Approved: Cost/Fee: \$256,586.00 LOE: 1,698

Work Assignment Manager Name: John Ravenscroft

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1101

FAX Number:

Project Office Name: Shirley Harrison

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name: Shirley Harrison

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Contracting Official Name: Sandra Stargardt-Bliss

*Sandra Stargardt-Bliss*  
(Signature) 4/27/12 (Date)

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-04

Other  Amendment Number: 1

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

QXRA Activities.....

Contractor

TCF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

Purpose

- Work Assignment
- Work Assignment Amendment
- Work Plan Approval
- Work Assignment Close-Out
- Incremental Funding

Period of Performance

From 01/01/2012 to 12/31/2012

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A

SFC (Max 2)

Line	DCN (Max 6)	Budget FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period 01/01/2011 To 12/31/2012

Cost/Fee:

LOF:

This Action:

Total

Work Plan / Cost Estimate Approvals

Contractor WP Dated 06/06/2012 Cost/Fee: \$24,871.00 LOF: 174

Cumulative Approved Cost/Fee: \$261,457.00 LOF: 1,872

Work Assignment Manager Name John Ravenscroft

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1101

FAX Number:

Project Officer Name Shirley Harrison

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name Shirley Harrison

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Contracting Official Name Sandra Stargardt-Lewis

*Sandra Lewis* 7/9/12  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-04

Other  Amendment Number: 1

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

QXRA Activities.....

Contractor

TCF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

Purpose

- Work Assignment
- Work Assignment Amendment
- Work Plan Approval
- Work Assignment Close-Out
- Incremental Funding

Period of Performance

From 01/01/2012 to 12/31/2012

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A

SFC (Max 2)

Line	DCN (Max 6)	Budget FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period 01/01/2011 To 12/31/2012

Cost/Fee:

LOF:

This Action:

Total

Work Plan / Cost Estimate Approvals

Contractor WP Dated 06/06/2012 Cost/Fee: \$24,871.00 LOF: 174

Cumulative Approved Cost/Fee: \$261,457.00 LOF: 1,872

Work Assignment Manager Name John Ravenscroft

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:  
Phone Number: 202-566-1101

FAX Number:

Project Officer Name Shirley Harrison

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:  
Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name Shirley Harrison

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:  
Phone Number: 202-566-1107

FAX Number:

Contracting Official Name Sandra Stargardt-Lewis

*Sandra Lewis* 7/9/12  
\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:  
Phone Number: 513-487-2006

FAX Number:

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-04

Other  Amendment Number: 2

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

QMRA Activities to Support Cri

Contractor:

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.6

Purpose:

- Work Assignment
- Work Assignment Close-Out
- Work Assignment Amendment
- Incremental Funding
- Work Plan Approval

Period of Performance

From 01/01/2012 to 12/31/2012

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO (Max 2)

Line	DCN (Max 5)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012

Cost/Fee:

LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 08/07/2012

Cost/Fee: \$59,939.00

LOE: 432

Cumulative Approved:

Cost/Fee: \$341,396.00

LOE: 2,304

Work Assignment Manager Name John Ravenscroft

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 202-566-1101

FAX Number:

Project Officer Name Shirley Harrison

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name

(Signature)

(Date)

Branch/Mail Code:

Phone Number:

FAX Number:

Contracting Official Name Sandra Stangardt-Louis

(Signature)

(Date) 8/28/12

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-04

Other  Amendment Number: 2

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

QMRA Activities to Support Cri

Contractor:

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.6

Purpose:

- Work Assignment
- Work Assignment Close-Out
- Work Assignment Amendment
- Incremental Funding
- Work Plan Approval

Period of Performance

From 01/01/2012 to 12/31/2012

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO (Max 2)

Line	DCN (Max 5)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012

Cost/Fee:

LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 08/07/2012

Cost/Fee: \$59,939.00

LOE: 432

Cumulative Approved:

Cost/Fee: \$341,396.00

LOE: 2,304

Work Assignment Manager Name John Ravenscroft

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 202-566-1101

FAX Number:

Project Officer Name Shirley Harrison

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name

(Signature)

(Date)

Branch/Mail Code:

Phone Number:

FAX Number:

Contracting Official Name Sandra Stangardt-Louis

(Signature)

(Date) 8/28/12

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-04

Other  Amendment Number:  
000003

Contract Number  
EP-C-11-005

Contract Period 01/01/2012 To 12/31/2012

Title of Work Assignment/SF Site Name

Base Option Period Number 1

QMRA Activities

Contractor  
ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW  
3.1, 3.3, 3.6

Purpose:  Work Assignment  Work Assignment Close-Out  
 Work Assignment Amendment  Incremental Funding  
 Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments:  
WORK ASSIGNMENT 1-04 HAVE BEEN FULLY FUNDED AT THE COST OF \$256,586

Superfund Accounting and Appropriations Data  Non-Superfund

SFO (Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2012 To 12/31/2012 Cost/Fee: LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name John Ravenscroft  
  
\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:  
Phone Number 202-566-1101  
FAX Number:

Project Officer Name Shirley Harrison  
  
\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:  
Phone Number: 202-566-1107  
FAX Number:

Other Agency Official Name  
  
\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:  
Phone Number:  
FAX Number:

Contracting Official Name Sandra Stargardt-Licis  
  
\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:  
Phone Number: 513-487-2006  
FAX Number:

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

07

Other  Amendment Number:

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

Children's Risks from Fecal Co

Contractor

ICE INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.6

Purpose:

- Work Assignment
- Work Assignment Close-Out
- Work Assignment Amendment
- Incremental Funding
- Work Plan Approval

Period of Performance

From 01/01/2012 to 12/31/2012

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-65A

S-O  
(Max 2)

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012 Cost/Fee: LOE:

This Action

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name John Ravenscroft

(Signature) (Date)

Branch/Mail Code:  
Phone Number 202-566-1101  
FAX Number:

Project Officer Name Shirley Harrison

(Signature) (Date)

Branch/Mail Code:  
Phone Number: 202-566-1107  
FAX Number:

Other Agency Official Name Shirley Harrison

(Signature) (Date)

Branch/Mail Code:  
Phone Number: 202-566-1107  
FAX Number:

Contracting Official Name Sandra Starckardt-Licis

(Signature) (Date) 8/7/12

Branch/Mail Code:  
Phone Number: 513-487-2006  
FAX Number:

**Performance Work Statement  
ICF Contract EP-C-11-005  
Work Assignment #1-07**

**Title:** Children's risks from fecal contamination in recreational water

**Work Assignment Manager:** John Ravenscroft (Mail Code 4304T)  
Health and Ecological Criteria Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Ave, N.W.  
Washington, DC 20460  
Phone (202) 566-1101  
E-mail: [ravenscroft.john@epa.gov](mailto:ravenscroft.john@epa.gov)

**Alternate WAM:**  
Shamima Akhter (Mail Code 4304T)  
Health and Ecological Criteria Division  
Office of Science and Technology, Office of Water  
1200 Pennsylvania Avenue, NW  
Washington DC, 20460  
Phone: 202-566-1341  
E-mail: [akhter.shamima@epa.gov](mailto:akhter.shamima@epa.gov)

**Period of Performance:** Work Assignment Issuance through December 31, 2012

**Contractor SOW:** 3.1, 3.3, 3.6

**\*\*Note: No CBI data will be needed in the course of this work assignment.**

**Goal:** The overall goal of this Performance Work Statement (PWS) is to examine multiple lines of evidence (Center for Disease Control (CDC) Recreational Water Illness outbreak data, risk assessment analyses and epidemiological data) to evaluate the potential that children have disproportionate risks of waterborne illness from recreational water contact.

**Objectives:**

1. Produce a comprehensive report for internal EPA evaluation detailing the known health information for children's waterborne illnesses from recreational water exposure. The report shall demonstrate an evaluation of the scientific literature, risk analysis (e.g., QMRA) and observational results (e.g., National Epidemiological and Environmental Assessment of Recreational Water (NEEAR) study reports).
2. Produce a draft and final report for external scientific peer review based on the information covered in objective 1.
3. Produce communications materials to accompany reports including: a one (1) to

two (2) page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the EPA WAM via technical direction.

### **Methodology:**

1. The Contractor shall combine previous efforts under WA B-07 and B-04 task 6.1 to compile a comprehensive evaluation of the potential health impacts on children from exposure to fecally-contaminated recreational water. This evaluation shall compare and contrast the potential health effects on the general population, as discussed in the current revisions of EPA's recreational water criteria for ambient waters.
2. The Contractor shall utilize the draft memos, including the data summary tables, prepared under WA B-07, including:
  - a. Children's health risks from infectious and pathogenic microorganisms
  - b. Identification of waterborne microorganisms associated with recreational water illness
  - c. Children's risks from fecal contamination in recreational water: epidemiological study review
  - d. Analysis of outbreak data for waterborne pathogens associated with recreational water illness in children: ambient/surface waters in the U.S.
3. The Contractor shall utilize the draft analysis detailed in the B-04 task 6.1 status update memo, "QMRA approaches to evaluate risks to sensitive subpopulations and children's health."
4. The Contractor shall specifically address the following questions in the conduct of this assignment :
  - a. Is there evidence for increased risk/illness for children compared to adults and/or the general population from exposure (any body contact; swimming, wading, ingestion, hand to mouth contact) to fecal contamination?
  - b. If so, can this difference be accounted for in recreational water quality determinations as measured by fecal indicator bacteria (FIB)?

**Background:** A growing body of scientific knowledge has demonstrated that children may suffer disproportionately from environmental health risks and safety risks. These risks occur because 1) children's neurological, immunological, digestive, and other bodily systems are still developing; 2) children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; 4) children's size and weight may diminish their protection from standard safety features; and 5) children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves.

The importance of identifying and assessing risks to children was made in Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risk<sup>1</sup>, which states:

“to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:

(a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.

1-102. Each independent regulatory agency is encouraged to participate in the implementation of this order and comply with its provisions.”

The U.S. Environmental Protection Agency (EPA)'s Policy on Evaluating Risks to Children<sup>2</sup> :

“considers the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done - for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination.”

The US EPA's Office of Children's Health Protection<sup>3</sup> conducts research and supports risk assessments to assess children's risks and susceptibility to environmental contaminants (chemicals, toxins, air pollutants). However, it not clear whether children suffer disproportionate exposures and health outcomes as a result of exposure to pathogens such as found in recreational surface waters. Few epidemiological data and quantitative risk assessments have explored children's risks from microbial contaminants found in water, limiting the ability to determine if children experience different responses to waterborne fecal indicators and pathogens, or develop illness rates as a result of recreational water contact in the United States. Risks in children have specifically not been explored separately, but they are included as part of the general populations in most epidemiological studies.

Under the auspices of the Clean Water Act (CWA), the Agency regulates recreational water, and sets numeric indicator bacteria criteria (*Escherichia coli*, Enterococci) in surface (ambient) waters used for the purpose of recreational water contact. The current

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<sup>1</sup> Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks. [http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe\\_executiv.htm](http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm)

<sup>2</sup> Policy on Evaluating Health Risks to Children. <http://www.epa.gov/osa/spc/pdfs/memohlth.pdf>

<sup>3</sup> The Office of Children's Health Protection. [http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe\\_executiv.htm](http://yosemite.epa.gov/ochp/ochpweb.nsf/content/whatwe_executiv.htm)

recreational water criteria were designed to protect swimmers (in general) from illnesses due to exposure to pathogens in recreational waters. The criteria developed in 1986 were mainly based on enumerations of fecal indicator bacteria (FIB) using culture-based methods. EPA is committed to develop new recreational water quality criteria for all water body types by 2012 and will address potentially disproportionate risks to children in the criteria development process.

Epidemiology studies have been conducted to describe and quantify the health effects associated with exposure to contaminated recreational waters. The primary goal of most of these studies has been to evaluate associations between measures of microbial water quality (usually quantified by measuring fecal indicator bacteria) and swimming-associated illness.

To address this issue, variations of two basic study designs have been used. For the purposes of this Work Assignment, these study designs are referred to as the “cohort” and the “randomized” design. The cohort design was used in the EPA epidemiology studies. The U.S. EPA, in collaboration with the Centers for Disease Control and Prevention have undertaken The National Epidemiological and Environmental Assessment of Recreational (NEEAR) Water Study to investigate human health effects and rapid water quality methods associated with recreational water use. A main goal of the NEEAR study is to determine how new ways of measuring fecal pollution can be used effectively to protect swimmers' health. The randomized design has been used in studies in Europe.

The approach of these designs differs in several critical aspects, some of which are summarized briefly below.

**Swimmer/non-swimmer assignment:**

The randomized design assigns “swimming” and non-swimming status by randomly assigning participants to each exposure group. The cohort design uses observed and self-reported swimming status. In the randomized design, swimmers are asked to swim completing specific activities such as immersing their head and/or staying in the water for a minimum amount of time at a designated position. In the cohort design, locations and swimming are assessed by interviewer and self-report.

**Target population:**

The EPA NEEAR cohort studies target the beach going population as their target population sample, and population of interest. Randomized trials often recruit subjects from nearby communities. Due to ethical issues, many randomized trial studies restrict their enrollment to adults 18 and over.

**Water quality assessment and exposure assignment:**

The randomized study usually attempts to assign individual exposures by intensively characterizing the water quality where an individual swimmer is exposed. However, there are known sampling and matrix issues with assigning water quality, as measured by fecal indicator bacteria, to individual swimmers.

Detection of indicator bacteria does not necessarily track the occurrence or distribution of pathogens that may or may not be present in the water column. Water quality in a cohort study is usually characterized by collecting samples in a fixed layout to assess average water quality over a given time/space dimension.

**Other differences:**

Because the cohort design is less intensive with regard to resources and investigator involvement, usually more subjects are enrolled over a wider range of days and environmental conditions. The EPA NEEAR Water Study has focused on FIB measured by novel and rapid analytical methods; whereas all published randomized designs have relied on traditional methods and approaches in measuring indicator bacteria.

**Quality Assurance:** The tasks in this PWS require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this PWS.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA WAM before activities covered by the additional QA language begin under this PWS..

**Performance Work Statement (PWS):** The scope in this PWS will fall under the following task areas:

***Task 1: Work Plan and monthly progress reports (MPR)***

*Task Area 1.1. Work Plan*

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

*Task Area 1.2. Monthly Progress Reports*

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoiced LOE and costs delineated by the

tasks in this WA. The Contractor shall provide the EPA WAM with weekly updates detailing progress. That updates shall be provided every Friday via email.

*Task Area 1.3. Information Quality Guidelines*

The Contractor shall ensure the products developed under this PWS comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this PWS as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this PWS. The Contractor shall provide the memo at the time it delivers the Final Report under Task 2.1. As directed by the EPA WAM, the Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist.

**Task Area 2: Project Reports**

*Task Area 2.1. Preparation of EPA report detailing results*

The Contractor shall prepare and submit a comprehensive report for under this task detailing the information collected and analyzed for the evaluation of human health risks to children from recreational exposure to fecal contamination. The report shall capture information evaluated as specified in the above sections.

The Contractor shall conduct a project planning meeting in conjunction with the EPA WAM prior to compiling the report. This meeting will include the following topics: how to utilize the existing information reported in the B-07 memos and B-04 QMRA to compile this report, identify any additional analyses that may be needed, how to detail the overall messages in an accessible format, what additional narrative needs to be developed to effectively communicate the analytical results and contextual public health message (i.e., incorporating effective risk communication tools in the report to engage both the technical and non-technical audiences), what additional communication materials would be needed (see Task 3), project scheduling, and other topics to be determined.

The report may undergo multiple edits and the Contractor is expected to respond to EPA comments. This document will need to be formatted as directed by the EPA WAM. The Contractor shall incorporate comments on any draft deliverables from EPA WAM. Also, the Contractor shall update information in the report as needed to capture any developments related to ongoing studies. The report shall be compliant with Section 508 of the Rehabilitation Act when finalized and submitted (see <http://www.epa.gov/accessibility/index.htm>).

*Task Area 2.2. Preparation of Report of External Scientific Peer Review*

The Contractor shall prepare and submit a version of the final report based on the deliverable under Task 2.1 that would be suitable for external scientific peer review. This task is subsequent to task 2.1. The Contractor shall submit a draft to the EPA WAM for Agency clearance. When all Agency comments have been addressed, that version may be submitted for peer review. The venue for the peer review is currently undetermined. The Contractor shall address peer reviewer comments in conjunction with the EPA WAM. This document will need to be formatted for publication as directed by the EPA WAM.

**Task Area 3: *Communication materials***

As specified in the above methodology section, the Contractor shall prepare, in conjunction with the EPA WAM, materials to assist in communicating the complex technical aspects of the project results to both non-technical and technical (but not academic) audiences (both internal and external to the Agency). These materials will most likely consist of synopses, executive summaries, Q&As, presentation slides, etc. and each may be aimed at a particular audience or tailored for the communication need. The Contractor shall coordinate with the EPA WAM on the scope and nature of these materials for specific audiences.

**Task Area 4: *General Project Support***

The Contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and/or other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The contractor may also be directed to participate in and/or conduct briefings and/or present at meetings. It is estimated that this task should not require more than 5 – 10 % of the total LOE allotted to this work assignment.

One of the outcomes of the project planning meeting detailed in Task 2.1 may be the identification of data or analysis gaps, particularly in regards to the QMRA analysis. For example, the finalized analysis of the NEEAR marine data was not completed at the time of the conduct of the QMRA under B-04, task 6. Although the final analysis of that data did not show a significant difference in illness response between children 12 and under and the general population, using this combined dataset may be helpful for the discussion of the QMRA portion of the deliverables under tasks 2.1 and 2.2. Should such analyses be identified as important based on the outcome of the project planning meeting, the EPA WAM will provide technical direction to ICF.

The Contractor shall plan on attending one presentation at EPA HQ at the draft report stage to discuss findings. All appropriate clearances and approvals required by Agency policy in support of any and all meetings shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under meeting-

related activities and expenses shall not occur until this approval is obtained and provided by the PO.

<b>Task No.</b>	<b>Milestones/Deliverable*</b>	<b>Schedule</b>
1	1.1 Workplan	Within 15 business days of receipt of WA
1	1.3 Information Quality Guidelines	Submitted with final deliverables
2	2.1 Project planning meeting.	Within 2 weeks of receipt of WA
2	2.1 Compile literature information and risk analyses; identify any remaining data/information gaps and ways to address in the report; *submit memos to EPA WAM discussing: 1) project plan for combining the children's health info and identify data and analysis gaps with remedial approach; and 2) communication strategy.	Within 2 weeks of 2.1 planning meeting
2	*2.1 Draft report for EPA review	Within 3weeks of 2.1 planning meeting
2	2.1 Respond to EPA reviewer comments	Within 2 weeks of receiving EPA comments
2	*2.1 Submit final report to EPA	Within 2 weeks of addressing comments
2	*2.2Submit draft report for EPA review	TBD based on outcome of Task 2.1
2	2.2 Respond to EPA reviewer comments	Within 2 weeks of receiving EPA comments
2	*2.2 Submit final report to EPA for peer review clearance	Within 2 weeks of addressing comments
3	Prepare risk communication presentation materials for technical and non-technical audiences	TBD by technical direction
4	General project support	TBD by technical direction

**Travel:** Local travel is required for contractor to attend one presentation at EPA HQ. Otherwise, *no* contractor travel outside of the Washington, D.C. metro area is anticipated for this PWS.

**Task Knowledge and Skills Required:** The Contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed. The Contractor shall also be proficient in R programming and other relevant statistical tools. The Contractor shall have practical

experience in environmental microbiology, epidemiology, and statistical methods and analysis and have advanced credentials in statistics or environmental engineering. The Contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development.

The Contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

**General Requirements of the Work Assignment and Schedule:**

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

## **Attachment 1**

### **QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA**

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

#### **SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES**

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

#### **SECTION 2.0, SOURCES OF SECONDARY DATA**

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

#### **SECTION 3.0. QUALITY OF SECONDARY DATA**

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)
- 3.2 The procedures for determining the quality of the secondary data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

#### **SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION**

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

## References

### CDC Rec Water Outbreaks:

#### Alphabetical index of Water-Related Health Data:

[http://www.cdc.gov/healthywater/statistics/surveillance/health\\_data.html](http://www.cdc.gov/healthywater/statistics/surveillance/health_data.html)

CDC Healthy Swimming Webpage: <http://www.cdc.gov/healthywater/swimming/data/>

### Epidemiological studies:

*“High Sensitivity of Children to Swimming-Associated Gastrointestinal Illness Results Using a Rapid Assay of Recreational Water Quality”* Timothy J. Wade, Rebecca L. Calderon, Kristen P. Brenner, Elizabeth Sams, Michael Beach, Richard Haugland, Larry Wymer, and Alfred P. Dufour (Epidemiology 2008;19: 375–383)

[http://journals.lww.com/epidem/Abstract/2008/05000/High\\_Sensitivity\\_of\\_Children\\_to\\_8.aspx](http://journals.lww.com/epidem/Abstract/2008/05000/High_Sensitivity_of_Children_to_8.aspx)

#### *Marine Studies (P1, 2):*

*“Rapidly measured indicators of recreational water quality and swimming-associated illness at marine beaches: A prospective cohort study”* Timothy J Wade , Elizabeth Sams, Kristen P Brenner , Rich Haugland , Eunice Chern , Michael Beach , Larry Wymer, Clifford C Rankin , David Love , Quanlin Li , Rachel Noble and Alfred P Dufour - Environmental Health 2010, 9:66doi:10.1186/1476-069X-9-66

Published: 31 October 2010

• Table S2: Adjusted Odds Ratios for illness risk among swimmers for a 1 log<sub>10</sub> Increase in indicator density. Children age 10 and under.

<http://www.ehjournal.net/imedia/3968942414721357/supp2.pdf>

#### *Epidemiological study in marine waters impacted by urban runoff in a temperate region (CD 5(a)):*

*“Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies”* Timothy J Wade , Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010. USEPA Report Number: EPA/600/R-10/168.

• Table 4.5, 4.6: Water exposures among children

• Tables 4.8-4.12: Incidence of illness among children

• Table 4.39, 4.42, 4.56, 4.57,

• Figure 5.16: Incidence of illness among children with regard to measures of water quality.

<http://water.epa.gov/scitech/swguidance/waterquality/standards/criteria/health/recreation/index.cfm>

#### *Epidemiological study in a tropical region (CD 5(b)):*

*"Report on 2009 National Epidemiologic and Environmental Assessment of Recreational Water Epidemiology Studies"* Timothy J Wade , Elizabeth A Sams, Rich Haugland, Kristen P Brenner, Quanlin Li, Larry Wymer, Marirosa Molina, Kevin Oshima and Alfred P Dufour. US Environmental Protection Agency, Office of Research and Development; 2010. USEPA Report Number: EPA/600/R-10/168.

Wade, T. J., R. L. Calderon, et al. (2006). "Rapidly measured indicators of recreational water quality are predictive of swimming-associated gastrointestinal illness." *Environ Health Perspect* 114(1): 24-8.

Wade, T. J., N. Pai, et al. (2003). "Do U.S. Environmental Protection Agency Water Quality Guidelines for Recreational Waters Prevent Gastrointestinal Illness? A Systematic Review and Meta-analysis." *Environmental Health Perspectives* 111(8): 1102-1109.

Colford, J. M., Jr., T. J. Wade, et al. (2007). "Water Quality Indicators and the Risk of Illness at Beaches With Nonpoint Sources of Fecal Contamination." *Epidemiology* 18(1): 27-35.

Fleisher, J. M., F. Jones, et al. (1993). "Water and non-water-related risk factors for gastroenteritis among bathers exposed to sewage-contaminated marine waters." *International Journal of Epidemiology* 22(4): 698-708.

Fleisher, J. M., D. Kay, et al. (1996). "Marine waters contaminated with domestic sewage: nonenteric illnesses associated with bather exposure in the United Kingdom." *Am J Public Health* 86(9): 1228-34.

Kay, D., J. M. Fleisher, et al. (1994). "Predicting likelihood of gastroenteritis from sea bathing: results from randomised exposure." *Lancet* 344(8927): 905-9.

Wiedenmann, A., P. Kruger, et al. (2006). "A randomized controlled trial assessing infectious disease risks from bathing in fresh recreational waters in relation to the concentration of *Escherichia coli*, intestinal enterococci, *Clostridium perfringens*, and somatic coliphages." *Environ Health Perspect* 114(2): 228-36.

Kay, D., N. Ashbolt, et al. (2006). "Reply to comments on "Derivation of numerical values for the World Health Organization guidelines for recreational waters"." *Water Res* 40(9): 1921-5.

Kay, D., J. Bartram, et al. (2004). "Derivation of numerical values for the World Health Organization guidelines for recreational waters." *Water Res* 38(5): 1296-304.

A description of EPI-BATHE can be found:  
<http://www.aber.ac.uk/iges/research/epibathe/favorite.htm>

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**Manager's Planning Checklist for Peer Review**

- 1) Title of Work Product: *Children's risk from fecal contamination in water*
- 2) What Decision/Rule/Regulation/Action Does this Work Product Support: *support for development and implementation of rec A/DL*
- 3) Designation of Scientific and Technical Work Products
- Is the work product scientific or technical yes no?
  - Is the work product influential scientific information (ISI), highly influential scientific assessment (HISA), or other? (See Section 2.2.3 and 2.2.4 of the Peer Review Handbook for an explanation of these terms).
- 4) Determining What Peer Review is Needed
- If ISI or HISA, peer review is needed.
  - If not influential, is peer review still needed?
  - What peer review mechanism is needed (internal and/or external)?
  - When does the review need to be done?
  - How much time will be needed to conduct/complete the review?
  - Are there court ordered deadlines or other constraints?
  - Has senior management (AA/RA/others) been informed of progress/problems?
  - What would constitute success for this review?
- 5) Determining the Resources for Peer Review
- What is the priority of this project relative to other projects in the same office?
  - What resources are needed to conduct the review?
  - What are the impacts of the review on personnel?
  - Who will lead the peer review?
  - Who will conduct the peer review?
  - Who will maintain the peer review record?
  - Where will the peer review record be kept?
  - What mechanism will be used for the peer review?
  - Has the charge been developed?
  - Has internal and external coordination been initiated/completed?
  - Have arrangements for interim/final sign off's (e.g., for the charge, the panel, on any changes to the final work product) been made?
  - How will results of the review be presented and addressed in the final work product (e.g., in a preamble, as an accompanying appendix – as well as changes in the work product itself)?
  - Has the work product been entered into the Science Inventory?
- 6) Comments: \_\_\_\_\_
-

<b>EPA</b> United States Environmental Protection Agency Washington, DC 20460		Work Assignment Number 1-07								
<b>Work Assignment</b>		<input type="checkbox"/> Other <input type="checkbox"/> Amendment Number								
Contract Number EP-C-11-005	Contract Period 01/01/2011 To 12/31/2012 Base                      Option Period Number 1	Title of Work Assignment/SF Site Name Children's Risks from Federal Co								
Contractor ICF INCORPORATED, I.L.C.	Specify Section and paragraph of Contract SOW 3.1, 3.3, 3.6									
Purpose <input type="checkbox"/> Work Assignment <input type="checkbox"/> Work Assignment Amendment <input checked="" type="checkbox"/> Work Plan Approval	<input type="checkbox"/> Work Assignment Close-Out <input type="checkbox"/> Incremental Funding	Period of Performance From 01/01/2012 to 12/31/2012								
Comments:										
<input type="checkbox"/> Superfund                      Accounting and Appropriations Data		<input checked="" type="checkbox"/> Non-Superfund								
Note: To report additional accounting and appropriations data use EPA Form 1800 89A.										
SFO (Max 2) <input type="checkbox"/>										
Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 3)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										
Authorized Work Assignment Ceiling										
Contract Period 01/01/2011 To 12/31/2012		Cost/Fee:		LOF:						
This Action:										
Total:										
Work Plan / Cost Estimate Approvals										
Contractor W/P Dated: 08/24/2012		Cost/Fee: \$39,026.00		LOF: 371						
Cumulative Approved:		Cost/Fee: \$39,026.00		LOF: 371						
Work Assignment Manager Name John Ravenscroft					Branch/Mail Code:					
_____ (Signature)                      (Date)					Phone Number: 202-566-1101					
_____ (Signature)                      (Date)					FAX Number:					
Project Officer Name Shirley Harrison					Branch/Mail Code:					
_____ (Signature)                      (Date)					Phone Number: 202-566-1107					
_____ (Signature)                      (Date)					FAX Number:					
Other Agency Official Name Shirley Harrison					Branch/Mail Code:					
_____ (Signature)                      (Date)					Phone Number: 202-566-1107					
_____ (Signature)                      (Date)					FAX Number:					
Contracting Official Name Sandra Stangardt-Lewis					Branch/Mail Code:					
<i>Sandra Lewis</i> (Signature)                      9/25/12 (Date)					Phone Number: 513-487-2006					
_____ (Signature)                      (Date)					FAX Number:					

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-08

Other

Amendment Number:

Contract Number

EP C 11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

AWQC for Pathogens

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.4, 3.6

Purpose

Work Assignment

Work Assignment Close-Out

Work Assignment Amendment

Incremental Funding

Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1600-69A

SFO (Max 2)

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 4)	Program Element (Max 3)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012

LOE: 0

This Action: 760

Total: 760

Work Plan / Cost Estimate Approvals

Contractor WP Dated: Cost/Fee: LOE:

Cumulative Approved: Cost/Fee: LOE:

Work Assignment Manager Name: Sharon Nappier

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Branch/Mail Code

Phone Number: 202-566-0740

FAX Number:

Project Officer Name: Shirley Harrison

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Branch/Mail Code

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name: Shirley Harrison

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Branch/Mail Code

Phone Number: 202-566-1107

FAX Number:

Contracting Official Name: Anna Reinhart

*Anna Reinhart*  
\_\_\_\_\_  
(Signature)

12/22/11  
\_\_\_\_\_  
(Date)

Branch/Mail Code

Phone Number: 513-487-2114

FAX Number:

**PERFORMANCE WORK STATEMENT  
ICF CONTRACT EP-C-11-005  
WORK ASSIGNMENT #1-08**

**Title:** Activities to support the development of Ambient Water Quality Criteria for Pathogens

**Work Assignment Manager:** Sharon Nappier (Mail Code 4304T)  
Health and Ecological Criteria Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460  
Phone (202) 566-0740  
E-mail: [nappier.sharon@epa.gov](mailto:nappier.sharon@epa.gov)

**Alternate WAM:** John Ravenscroft (Mail Code 4304T)  
Health and Ecological Criteria Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Ave, N.W.  
Washington, DC 20460  
Phone (202) 566-1101  
E-mail: [ravenscroft.john@epa.gov](mailto:ravenscroft.john@epa.gov)

**Period of Performance:** January 1, 2012 through December 31, 2012

**LOE:** 760 hours

**Contractor SOW:** 3.1, 3.3, 3.4, 3.6

**\*\*Note: No CBI data will be needed in the course of this work assignment.**

**Background:**

Human health ambient water quality criteria (AWQC) are numeric values limiting the amount of chemical or microbial agents present in our nation's waters. Human health criteria are developed under Section 304(a) of the Clean Water Act of 1972 and are designed to protect human health. Water quality criteria are developed by assessing the relationship between pollutants and their effect on human health and the environment. These criteria are used by states and Indian tribes to establish water quality standards and ultimately provide a basis for controlling discharges or releases of pollutants.

EPA has published AWQC for bacteria. Historically EPA has based the bacteria criteria on fecal indicator bacteria (FIB). These organisms do not cause human illness themselves (that is, they are not human pathogens); rather, they are merely indicators

of fecal contamination and therefore indicators of the potential presence of human pathogenic organisms.

The EPA is now interested in creating ambient water quality criteria (AQWC) for Pathogens. EPA believes that these Pathogen Criteria must be scientifically sound, implementable for broad CWA purposes, and provide for improved public health protection.

### **Quality Assurance:**

Tasks 2-4 in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must follow procedures outlined in the approved project-specific QAPP to assure the quality of the secondary data and other data collected to be used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports and should follow Attachment 1 titled, QAPP Requirements for projects using secondary data.

**Statement of Work:** The scope of work in this assignment will fall under the following task areas:

#### **TASK 1 – Workplan and Monthly Progress Reports**

The Contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the Contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the Contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The Contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

#### **Task 2 - Re-evaluate, Update, and Finalize the *Methodology for Deriving Microbial Ambient Water Quality Criteria (AWQC) for Recreational Designated Uses for the Protection of Human Health***

In 2006, EPA drafted the recommended *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*. The Microbial

Methodology is guidance for scientific human health assessments used by EPA to develop, publish, and revise, recommended criteria for water quality accurately reflecting the latest scientific knowledge. The recommended criteria would serve states' and tribes' needs in their development of water quality standards under §303(c) of the CWA.

The Contractor shall finalize the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health* for publication. The most recent document underwent External Peer Review in 2006. However, the Contractor shall update and re-evaluate the document to reflect the most recent draft *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media* and the current scientific literature. Process steps for re-evaluating, updating, and finalizing the document will be provided through Technical Direction.

### **TASK 3 – Ambient Water Quality Criteria for Pathogens**

#### ***Task 3.1 Scope of the Criteria Documents***

This task will require the Contractor to assist scoping the AWQC for Pathogens for recreational designated uses. Pathogens of immediate interest include, but are not limited to, viruses and protozoa. EPA is considering one criterion document for viruses, such as enteroviruses and noroviruses, and another for protozoan pathogens, such as cryptosporidium and giardia. The Contractor shall assist in drafting an outline of pathogen criteria for viral and protozoan pathogens and identifying the needs of the criterion documents.

#### ***Task 3.2 Derivation of the Criteria Values***

Drawing on the draft *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media* and the *Methodology for Deriving Microbial AWQC for Recreational Designated Uses for the Protection of Human Health*, the Contractor shall develop AWQC values for the pathogens of interest. Specific pathogens and the order of importance will be provided through Technical Direction.

#### ***Task 3.3 Develop Criterion Document Drafts***

The Contractor shall provide draft documents of the AWQC for Pathogens. Again, specific pathogens and the order of importance will be provided through Technical Direction. This task will be an ongoing effort for the period of performance of this work assignment and a series of Drafts are expected.

#### ***Task 3.4 Prepare and submit Final AWQC Criterion for Pathogens***

The Contractor shall prepare and submit a Final RWQC document. This document will

need to be 508 Compliant and formatted as directed by the EPA WAM.

**Task 3.5.** Prepare briefing materials and other supporting documents pertaining to the Pathogen Criteria documents

Briefing materials and other supporting documents will be needed during the Criteria development process. The Contractor shall aid the in the development of any materials or presentations for these purposes.

*Travel:* No contractor travel outside of the Washington, D.C. metro area is anticipated for this task.

**Task 4 - General Project Support**

The Contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project update and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The Contractor may be requested to participate in and/or conduct briefings. A weekly update call with the EPA WAM will be required for this work assignment, as needed.

*Travel:* Travel may be needed as deemed necessary by the EPA WAM. No Contractor travel outside of the Washington, D.C. metro area is required.

**SCHEDULE AND DELIVERABLES:**

Task No.	DELIVERABLE	Schedule
1	1.1 Work Plan	Within <u>15 calendar</u> days of receipt of WA
2	2.0 Re-evaluate, update, and finalize the <i>Methodology for Deriving Microbial Ambient Water Quality Criteria for Recreational Designated Uses for the Protection of Human Health</i>	TBD
3	3.1 Scope of the Criteria documents	TBD
3	3.2 Derivation of the Criteria Values	TBD
	3.3 Develop Criteria Document Drafts	TBD
3	3.4 Submit Final AWQC Criterion for Pathogens	TBD
3	3.5 Prepare briefing materials and other supporting documents	TBD
4	4.0 General Project Support	TBD

**Knowledge and Skills Required:** Contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this work assignment. The Contractor shall have practical experience in conducting microbial risk assessments and have advanced credentials in environmental microbiology and/or environmental engineering. The Contractor shall be familiar with the use of fecal indicator organisms, microbiological analytical methods (including molecular techniques), water monitoring applications of epidemiological data, determination of human exposure to environmental contaminant sources, and gastrointestinal disease endpoints.

**General Requirements of the Work Assignment and Schedule:**

**Due Dates:** The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

**Delays:** The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

**Draft Documents:** The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

**Final Documents:** The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

## **Attachment 1**

### **QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA**

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

#### **SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES**

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation; as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, ~~statistical~~ data analysis (i.e. statistical analysis & any other types of data analysis), and assumptions/recommendations based on the data analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

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- 2.3 The sources of the secondary data will be identified in any project deliverable.

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- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)
- 3.2 The procedures for determining the quality of the secondary data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

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- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

EPA

United States Environmental Protection Agency  
Washington DC 20460

Work Assignment

Work Assignment Number

1-08

Other  Amendment Number:

Contract Number

EP-R-11-005

Contract Period: 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

1-08, Support for Virus Critic

Contractor

ICF INCORPORATED, L.L.C.

Spec'y Section and paragraph of Contract SOW

3.1, 3.3, 3.4, 3.6

Purpose

Work Assignment

Work Assignment Close Out

Work Assignment Amendment

Incremental Funding

Work Plan Approval

Period of Performance

From: 01/01/2012 To 12/31/2012

Comments

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. All other conference related activities shall not occur until approval.

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900 69A.

SFO  
(Max 2)

Line	DCN (Max 6)	Budget/FY (Max 4)	Approval Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Conts)	Est/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 To 12/31/2012

Cost/Fee

LOB

This Action:

Total

Work Plan / Cost Estimate Approvals

Contractor WP Dated

01/07/2012

Cost/Fee: \$98,714.00

LOB: 760

Cumulative Approved:

Cost/Fee: \$98,714.00

LOB: 760

Work Assignment Manager Name: Sharon Nappier

Branch/Mail Code:

Phone Number: 214-760-3740

FAX Number:

(Signature)

(Date)

Project Officer Name: Shirley Harrison

Branch/Mail Code:

Phone Number: 202-760-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name: Shirley Harrison

Branch/Mail Code:

Phone Number: 214-760-1107

FAX Number:

(Signature)

(Date)

Contracting Official Name: Sandy L. ...

Branch/Mail Code:

Phone Number: 512-760-2006

FAX Number:

(Signature)

(Date)

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-08

Other

Amendment Number:

000001

Contract Number

EP-C-11-005

Contract Period 01/01/2011 to 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

Ambient Water Quality Criteria

Contractor

ICF INCORPORATED, I.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.4, 3.6

Purpose:

Work Assignment

Work Assignment Close-Out

Period of Performance

Work Assignment Amendment

Incremental Funding

From 01/01/2012 to 12/31/2012

Work Plan Approval

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1800-69A.

SFO  
(Max 2)

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 4)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 To 12/31/2012

Cost/Fee:

LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved:

Cost/Fee:

LOE:

Work Assignment Manager Name Sharon Nappier

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Branch/Mail Code:

Phone Number: 202-566-0740

FAX Number:

Project Officer Name Shirley Harrison

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name Shirley Harrison

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Contracting Official Name Sandra Stargard-Lewis

*Sandra Lewis*  
(Signature)

8/9/12  
(Date)

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

**PERFORMANCE WORK STATEMENT  
ICF CONTRACT EP-C-11-005  
WORK ASSIGNMENT #1-08 Amd 1**

**Title:** Activities to support the development of Ambient Water Quality Criteria for Pathogens

**Work Assignment Manager:** Sharon Nappier (Mail Code 4304T)  
Health and Ecological Criteria Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460  
Phone (202) 566-0740  
E-mail: [nappier.sharon@epa.gov](mailto:nappier.sharon@epa.gov)

**Alternate WAM:** John Ravenscroft (Mail Code 4304T)  
Health and Ecological Criteria Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Ave, N.W.  
Washington, DC 20460  
Phone (202) 566-1101  
E-mail: [ravenscroft.john@epa.gov](mailto:ravenscroft.john@epa.gov)

**Period of Performance:** Performance Work Statement (Amd) thru December 31, 2012

**Purpose of Amendment:** The purpose of this amendment is to add LOE hours and funding for the following Tasks below.

**TASK 1 – Workplan and Monthly Progress Reports - No changes – task remains the same.**

**Task 2 - Re-evaluate, Update, and Finalize the *Methodology for Deriving Microbial Ambient Water Quality Criteria (AWQC) for Recreational Designated Uses for the Protection of Human Health***

*Re-evaluate, update, and finalize Methodology for Deriving Microbial Ambient Water Quality Criteria (AWQC) for Recreational Designated Uses for the Protection of Human Health document and specifically evaluate how QMRA may be used to derive pathogen criteria values.*

### TASK 3 – Ambient Water Quality Criteria for Pathogens

#### *Task Area 3.1 Scope of the Criteria Documents*

*As part of scoping the Criteria documents, support the drafting of literature reviews and human health assessment documents to support future ambient water quality criteria for viruses. In the near-term, we are interested in evaluating bacteriophages and noroviruses.*

*Both literature reviews will likely undergo several internal reviews, drafts, and potentially external peer-review. The Contractor shall be required to edit multiple versions, as needed.*

*No additional changes to Task 3– other sub-tasks remain the same.*

#### **Task Area 4 - General Project Support - No changes – task remains the same.**

Task No.	DELIVERABLE	Schedule
		Within 10 business days of receipt of WA
	Develop a literature review on the current status of water quality criteria for viruses, including a list of viruses and their associated health effects.	December 15 2012
	Develop a literature review on the current status of water quality criteria for bacteriophages and noroviruses.	December 15 2012
	Develop a literature review on the current status of water quality criteria for other pathogens.	September 31 2012
	Develop a literature review on the current status of water quality criteria for other pathogens.	December 15 2012
	Develop a literature review on the current status of water quality criteria for other pathogens.	December 15 2012
	Develop a literature review on the current status of water quality criteria for other pathogens.	TBD
	Develop a literature review on the current status of water quality criteria for other pathogens.	TBD
	Develop a literature review on the current status of water quality criteria for other pathogens.	TBD
	Develop a literature review on the current status of water quality criteria for other pathogens.	TBD

**Quality Assurance:** same as the original PWS.

**Knowledge and Skills Required:** same as the original PWS.

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-08

Other  Amendment Number: 1

Contract Number

EP-C-11-005

Contract Period

01/01/2011 to 12/31/2012

Title of Work Assignment/SF Site Name

Virus Criteria

Contractor

ICE INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

Purpose:

Work Assignment

Work Assignment Close Out

Work Assignment Amendment

Incremental Funding

Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A

SFC  
(Max 2)

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 to 12/31/2012

Cost/Fee

LOE:

This Action

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

08/23/2012

Cost/Fee: \$92,600.00

LOE: 854

Cumulative Approved

Cost/Fee \$191,314.00

LOE: 1,614

Work Assignment Manager Name Sharon Nappier

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Branch/Mail Code:

Phone Number: 202-566-0740

FAX Number:

Project Officer Name Shirley Harrison

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name Shirley Harrison

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Contacting Official Name Sandy Licitis

*Sandy Licitis*  
(Signature)

9/13/2012  
(Date)

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-09

Other  Amendment Number

Contract Number

EP-0-11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

Human Health Assessment: Crypt

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

2.2, 3.1.6, 3.1.8

Purpose

Work Assignment

Work Assignment Close-Out

Work Assignment Amendment

Incremental Funding

Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A

SFO  
(Max 2)

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 5)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period:

01/01/2011 To 12/31/2012

Cost/Fee:

LOE:

This Action

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated:

Cost/Fee:

LOE:

Cumulative Approved

Cost/Fee:

LOE:

Work Assignment Manager Name Shamima Akhter

(Signature)

(Date)

Branch/Mail Code:

Phone Number 202-566-0000

FAX Number:

Project Officer Name Shirley Harrison

(Signature)

(Date)

Branch/Mail Code:

Phone Number 202-566-1107

FAX Number:

Other Agency Official Name Shirley Harrison

(Signature)

(Date)

Branch/Mail Code:

Phone Number 202-566-1107

FAX Number:

Contracting Official Name Sandra Stancardt-Licis

(Signature)

(Date)

Branch/Mail Code:

Phone Number 513-487-2006

FAX Number:

**PERFORMANCE WORK STATEMENT  
ICF CONTRACT EP-C-11-005  
WORK ASSIGNMENT # 1-09**

**Title:** Human Health Assessment: *Cryptosporidium* and *Giardia* in drinking and ambient water

**Work Assignment Manager:** Shamima Akhter  
Health and Ecological Criteria Division (Mail Code 4304T)  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Ave, N.W.  
Washington, DC 20460  
Phone (202) 566-1341  
E-mail: [akhter.shamima@epa.gov](mailto:akhter.shamima@epa.gov)

**Alternate WAM:** John Ravenscroft  
Health and Ecological Criteria Division (Mail Code 4304T)  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Ave, N.W.  
Washington, DC 20460  
Phone (202) 566-1101  
E-mail: [ravenscroft.john@epa.gov](mailto:ravenscroft.john@epa.gov)

**Period of Performance:** Work Assignment Issuance through December 31, 2012

**Contractor SOW:** 2.2, 3.1.6, and 3.1.8

**Background:**

The mission of the U.S. Environmental Protection Agency's (EPA) Office of Water is to protect public health and the environment from adverse effects of pollutants (e.g., toxic chemicals and microbial pathogens) in ambient water, drinking water, wastewater, sewage sludge and sediments. The Safe Drinking Water Act (SDWA) requires the EPA to regulate disease-causing organisms (pathogens) and toxic chemicals in drinking water.

The Safe Drinking Water Act requires the U.S. Environmental Protection Agency (EPA) to publish regulations to control disease-causing organisms (pathogens) and hazardous chemicals in drinking water. One of the regulations published by EPA to control pathogens is known as the Surface Water Treatment Rule (54 FR 27486; June 29, 1989). The purpose of the Long Term 2 (LT2) rule is to reduce illness linked with the contaminant *Cryptosporidium*, *Giardia* and other disease-causing microorganisms in drinking water. Under the LT 2 Rule *Cryptosporidium* oocysts at or below 0.075 oocysts/liter are considered the maximum value under which conventional drinking water treatment is expected to be capable of providing protection of consumers drinking up to 1.2 liters of water per day. Under the Safe Drinking Water Act's Surface Water Treatment Rule (further referred to as the Rule) *Giardia* cyst Maximum Contaminant Level Goal (MCLG) levels are set at "0" for treated water. In order to meet this requirement, *Giardia* cyst removal by conventional drinking water treatment must be able to reduce cyst levels by 3 orders of magnitude (3 logs) from source waters to insure protection of

consumers drinking up to 2.0 liters of water per day.

*Cryptosporidium* is a significant concern in drinking water because it contaminates surface waters used as drinking water sources, it is resistant to chlorine and other disinfectants, and it has caused waterborne disease outbreaks. Consuming water with *Cryptosporidium*, a contaminant in drinking water sources, can cause gastrointestinal illness (e.g., diarrhea, vomiting, cramps) and other health risk, which may be severe in people with weakened immune systems (e.g., infants and the elderly) and sometimes fatal in people with severely compromised immune systems (e.g., cancer and AIDS patients).

*Cryptosporidium* oocysts are common and widespread in ambient water and can persist for months in this environment. The dose that can infect humans is low, and a number of waterborne disease outbreaks caused by this protozoan have occurred in the U.S., most notably in Milwaukee, where an estimated 400,000 people became ill. The healthy people recover within several weeks after becoming ill, but illness may persist and contribute to death in those whose immune systems have been seriously weakened (e.g., AIDS patients). Drugs effective in preventing or controlling this disease are not yet available. The public health concern is worsened by the resistance of *Cryptosporidium* to water disinfection practices by chlorination, although oocysts can be inactivated by ozone and ultraviolet irradiation. However, a well-operated water filtration system is capable of removing at least 99 of 100 *Cryptosporidium* oocysts in the water. Monitoring for this organism in water is currently difficult and expensive.

The purpose of these documents is to serve as informal technical guidance to assist Federal, state, and local officials responsible for protecting public health when emergency spills or contamination situations occur.

**Quality Assurance:** Tasks 2-3 in this work assignment require the use of secondary data and require a QAPP specific to the activities being conducted. Consistent with the Agency's quality assurance (QA) requirements, the contractor must supplement the quality assurance project plan (QAPP), required under Task 1 of this work assignment, to assure the quality of the secondary data and other data collected to be used under this work assignment. The QAPP must be approved by the EPA before activities using secondary data begin.

The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports as specified under Task 1 and should follow the attachment titled, QAPP Requirements for projects using secondary data.

**Performance Work Statement:** The scope of the work in this Performance Work Statement (PWS) will fall under the following task areas:

### **Task 1: Work plan and monthly progress reports**

#### **Task Area 1.1. Work Plan**

The contractor shall develop a detailed work plan and cost estimate for each task outlined in this work assignment. The plan should contain, but not limited to, work-flowchart,

elaborate schedule (task-wise), staffing plan and qualifications of proposed staff, budget for each task and level of effort (LOE). Prior to the submission of the work plan, the contractor shall consult with the EPA WAM via conference call to mitigate any potential issues that need clarifications. The contractor shall include information on plans to manage work and control contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate, in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs' broken out by the tasks in this WA.

### **Task Area 1.2. Develop project specific QAPP**

Tasks 2-3 in this PWS require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor must comply with the contract level quality assurance project plan (QAPP) dated March 2012 to assure the quality and analyze of the secondary data and other data collected to be used under this work assignment. The project specific quality assurance requirements must be addressed in the work plan and monthly progress reports.

The work plan shall explain if any additional QA supplemental information will be submitted based on the specific data requirements of the WA. All projects in Tasks 2-3 that involve secondary data must comply with the approved contract level QAPP prior to the commencement of work.

## **Task 2: Develop Health Assessment document: *Cryptosporidium***

### ***2.1 Literature search***

In order to develop the document for *Cryptosporidium*, a thorough literature search, retrieval, and characterization of the data base on *Cryptosporidium* need to be conducted. It is noted that EPA WAM will conduct In-house literature search from 2006 until now and will provide full articles to the contractor through CD or electronically. The literatures prior to 2006 are available at the *Cryptosporidium* Risk Assessment document generated by the ICF. The contractor is advised to include those literatures, if needed for the health assessment document.

### ***2.2 Develop analysis plan and conduct exposure and dose response analysis***

Historical technical data that was used to generate the LT2 will be obtained from the EPA's Water Docket.

The health assessment document shall be comprised of a comprehensive review of published literatures on *Cryptosporidium* providing all relevant information, the general

characteristics of this protozoan, its occurrence in human and animal populations and in water, drinking water exposures, dose response, the health effects associated with *Cryptosporidium* infection are important features of the health assessment and all data of this nature should be captured from both US and foreign data bases. The EPA WAM will provide the *outline for the drinking and ambient water health assessments* to the contractor. The contractor shall evaluate several different permutations of the available feeding study dose response information for various strains and their combination. The contractor shall also estimate dose based upon 1.2 and 2.0 liters of water/day.

The contractor shall coordinate with the EPA WAM in the collection of datasets for exposure and dose response from various sources for the analysis. Collection of datasets will be conducted such that the Office of Management and Budget (OMB) Information Collection Rule (ICR) will not be triggered.

### ***2.3 Submit draft report of initial findings***

The contractor shall prepare a draft *Cryptosporidium* health assessment document for EPA WAM to review. The contractor shall insure that all factors that were applied to the health assessment are stated and are transparent throughout the document. It is EPA's concern that contractor shall include a list of references used for this task. In addition, the contractor shall also include a list of unused references along with clear justification for not using them. The contractor shall coordinate with the EPA WAM as inclusion or exclusion of any references to the draft document.

### ***2.4 Incorporate EPA comments and additional studies***

The EPA WAM will periodically search diverse data bases for potential new information and will provide to the contractor. The contractor shall incorporate any additional studies into revisions to draft report upon receipt from EPA WAM. It is the goal of the EPA WAM to gather as many examples as possible and available to help inform the policy development process. The contractor shall also incorporate EPA WAM's review comments to the document.

### ***2.5 Submit revised report***

The contractor shall revise and finalize the health assessment document based upon EPA WAM's review comments.

### ***2.6 Communication piece***

The contractor shall provide a brief communication (1- 3 pages) which will aid in briefing manager and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

### ***2.7 Response to the Peer Reviewer comments***

Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report.

### ***2.8 Incorporate Peer Reviewer comments to the documents***

The contractor shall incorporate all recommended edits and modifications to the documents. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review.

### ***2.9 Submit Final Report***

Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

## **Task 3: Develop Health Assessment document: *Giardia***

### ***3.1 Literature search***

In order to develop the document for *Giardia*, a thorough literature search, retrieval, and characterization of the data base on *Giardia* need to be conducted. It is noted that EPA WAM will conduct In-house literature search from 2006 until now and will provide full articles to the contractor through CD or electronically. The literatures prior to 2006 are available at the *Giardia* Risk Assessment document generated by the ICF. The contractor is advised to include those literatures, if needed for the health assessment document.

### ***3.2 Develop analysis plan and conduct exposure and dose response analysis***

Historical technical data that was used to generate the LT2 will be obtained from the EPA's Water Docket.

The health assessment document shall be comprised of a comprehensive review of published literatures on *Giardia* providing all relevant information, the general characteristics of this protozoan, its occurrence in human and animal populations and in water, drinking water exposures, dose response, the health effects associated with *Giardia* infection are important features of the health assessment and all data of this nature should be captured from both US and foreign data bases. The EPA WAM will provide the *outline for the drinking and ambient water health assessments* to the contractor. The contractor shall also estimate dose based upon 1.2 and 2.0 liters of water/day.

The contractor shall coordinate with the EPA WAM in the collection of datasets for exposure and dose response from various sources for the analysis. Collection of datasets

will be conducted such that the Office of Management and Budget (OMB) Information Collection Rule (ICR) will not be triggered.

### ***3.3 Submit draft report of initial findings***

The contractor shall prepare a draft *Giardia* health assessment document for EPA WAM's review. The contractor shall insure that all factors that were applied to the health assessment are stated and are transparent throughout the document. It is EPA's concern that contractor shall include a list of references used for this task. In addition, the contractor shall also include a list of unused references along with clear justification for not using them. The contractor shall coordinate with the EPA WAM as inclusion or exclusion of any references to the draft document.

### ***3.4 Incorporate EPA comments and additional studies***

The EPA WAM will periodically search diverse data bases for potential new information and will provide to the contractor. The contractor shall incorporate any additional studies into revisions to draft report upon receipt from EPA WAM. It is the goal of the EPA WAM to gather as many examples as possible and available to help inform the policy development process. The contractor shall also incorporate EPA WAM's review comments to the document.

### ***3.5 Submit revised report***

The contractor shall revise and finalize the health assessment document based upon EPA WAM's review comments.

### ***3.6 Communication piece***

The contractor shall provide a brief communication (1- 3 pages) which will aid in briefing manager and senior managers. The communication piece shall be written in plain English language for non-technical people and the relevant scientific studies shall be included as an attachment.

### ***3.7 Response to the Peer Reviewer comments***

Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report.

### 3.8 Incorporate Peer Reviewer comments to the documents

The contractor shall incorporate all recommended edits and modifications to the documents. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review.

### 3.9 Submit Final Report

Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

**Period of Performance/Milestones:** It is the Contractor's responsibility to coordinate with EPA WAM while conducting these tasks.

Task	Milestone	Date due
1	1.1 Work Plan	Within 2 weeks of receipt of WA
1	1.2 QAPP	Within 2 weeks of receipt of WA
1	Kick-off meeting with EPA WAM	1 week after WP approval
2.1	EPA will provide literatures and outline for the Health Assessment document	1 week after WP approval
2.2	Develop analysis plan and conduct exposure and dose response analysis	3 Weeks after WP approval
2.3	Submit draft report of initial findings	1 month after WP approval
2.4	Incorporate EPA comments and additional studies, if identified	1.5 months after WP approval
2.5	Submit revised report	2 months after WP approval
2.6	Communication Piece	TBD
2.7	Response to the Peer Reviewer comments	TBD
2.8	Incorporate Peer Reviewer comments	TBD
2.9	Submit final report	TBD
3.1	EPA will provide literatures and outline for the Health Assessment document	1 week after WP approval
3.2	Develop analysis plan and conduct exposure and dose response analysis	3 Weeks after WP approval
3.3	Submit draft report of initial findings	1 month after WP approval
3.4	Incorporate EPA comments and additional studies, if identified	1.5 months after WP approval
3.5	Submit revised report	2 months after WP approval
3.6	Communication Piece	TBD
3.7	Response to the Peer Reviewer comments	TBD
3.8	Incorporate Peer Reviewer comments	TBD
3.9	Submit final report	TBD

**Knowledge and Skills Required:** The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this PWS. The contractor shall be an accomplished microbial risk assessor with experience in environmental media, especially water. The contractor shall have knowledge and experience with the *Cryptosporidium* and *Giardia spp.* protozoa in water and water/wastewater treatment/disinfection effectiveness. The contractor shall be experienced in evaluation of data bases, statistics, and modeling regarding human exposure, dose response and health effects for application in microbial risk assessments.

**General Requirements of the Work Assignment and Schedule:**

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Final Documents: The Contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the COR will provide appropriate technical direction.

Final Peer Reviewed Document: Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review. Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

## **Attachment 1**

### **QAPP REQUIREMENTS FOR PROJECTS USING SECONDARY DATA**

A secondary data project involves the gathering and/or use of existing environmental data for purposes other than those for which they were originally collected. These secondary data may be obtained from many sources, including literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. For these projects, a QAPP shall be prepared to include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

#### **SECTION 1.0, PROJECT OBJECTIVES, ORGANIZATION, AND RESPONSIBILITIES**

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical analysis, if applicable, shall be included.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

#### **SECTION 2.0, SOURCES OF SECONDARY DATA**

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

#### **SECTION 3.0, QUALITY OF SECONDARY DATA**

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if applicable. (If appropriate, a related QAPP containing this information can be referenced.)
- 3.2 The procedures for determining the quality of the secondary data shall be described.

- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

#### **SECTION 4.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION**

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

**Knowledge and Skills Required:** The contractor shall have expertise in preparing the aforementioned materials and be knowledgeable with the various fields of discipline discussed in this PWS. The contractor shall be an accomplished microbial risk assessor with experience in environmental media, especially water. The contractor shall have knowledge and experience with the *Cryptosporidium* and *Giardia spp.* protozoa in water and water/wastewater treatment/disinfection effectiveness. The contractor shall be experienced in evaluation of data bases, statistics, and modeling regarding human exposure, dose response and health effects for application in microbial risk assessments.

**General Requirements of the Work Assignment and Schedule:**

**Due Dates:** The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

**Delays:** The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

**Draft Documents:** The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

**Final Documents:** The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

**Final Documents:** The Contractor shall revise and incorporate all EPA's comments and submit final documents both electronically and in hardcopy (Microsoft version 2003 or higher) to EPA WAM. The Agency may decide to publish the report on the web. If this occurs, the report will need to be 508 compliant and the COR will provide appropriate technical direction.

**Final Peer Reviewed Document:** Upon receipt of the EPA's external expert peer-review of the Contractor's Final Written Report, the EPA WAM will provide the Contractor with the recommended edits and modifications. The Contractor shall address all recommended peer-review modifications. Changes will be documented in a separate report for the record to describe how the peer-review comments were incorporated into the final report. The Contractor shall provide the revised final report (and documented changes to the report) to the EPA WAM for review. Upon the EPA WAM's approval, the Contractor shall send the final revised peer-reviewed report in Microsoft Word, version 2003 or higher, to the EPA WAM.

**Meetings, conferences, training events, award ceremonies and receptions:**

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

09

Other  Amendment Number:

Contract Number

EP-C-11-005

Contract Period 01/01/2012 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

Human Health Assessment: Crypt

Contractor

ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

2.2, 3.1.6, and 3.1.8

Purpose:

- Work Assignment
- Work Assignment Close-Out
- Work Assignment Amendment
- Incremental Funding
- Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO (Max 2)

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period 01/01/2012 To 12/31/2012 Cost/Fee: LOE

This Action

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 08/07/2012 Cost/Fee: \$69,368.00 LOE: 712

Cumulative Approved: Cost/Fee \$69,368.00 LOE: 712

Work Assignment Manager Name Shamima Akhter

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number 202-566-0000

FAX Number:

Project Officer Name Shirley Harrison

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name Shirley Harrison

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Contracting Official Name Sandra Stuardt-Licis

  
(Signature) 8/28/12 (Date)

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-10

Other  Amendment Number

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

Secondary Contact WQS-Pathogen

Contractor

ICF INCORPORATED, I.T.C.

Specify Section and paragraph of Contract SCW

3.1, 3.3, 3.4

Purpose

- Work Assignment
- Work Assignment Close Out
- Work Assignment Amendment
- Incremental Funding
- Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFC  
(Max 2)

Line	DCN (Max 6)	Budget FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period 01/01/2011 to 12/31/2012 Cost/fee: LOE.

This Action:

Total

Work Plan / Cost Estimate Approvals

Contractor WP Dated Cost/fee: LOE.

Cumulative Approved Cost/fee LOE.

Work Assignment Manager Name Gary Russo

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1335

FAX Number:

Project Officer Name Shirley Harrison

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name Shirley Harrison

\_\_\_\_\_  
(Signature) (Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Contracting Official Name Sandra Starnardt-Lewis

*Sandra Starnardt-Lewis*  
(Signature) 8/28/12  
(Date)

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

**PERFORMANCE WORK STATEMENT  
ICF CONTRACT EP-C-11-005  
WORK ASSIGNMENT #1-10**

**Title:** Secondary Contact Water Quality Standards for Pathogens

**Work Assignment Manager:** Gary Russo (Mail Code 4305T)  
Standards and Health Protection Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460  
Phone (202) 566-1335  
E-mail: [russo.gary@epa.gov](mailto:russo.gary@epa.gov)

**Alternate WAM:** Sharon Nappier (Mail Code 4304T)  
Health and Ecological Criteria Division  
Office of Water, Office of Science and Technology  
1200 Pennsylvania Avenue, N.W.  
Washington, DC 20460  
Phone (202) 566-0740  
E-mail: [nappier.sharon@epa.gov](mailto:nappier.sharon@epa.gov)

**Period of Performance:** Work assignment issuance through October 31, 2012

**Contractor SOW:** 3.1, 3.3, and 3.4

**CBI: No confidential business information will be needed for this work assignment.**

**Background:**

An effort is currently underway to revise EPA's bacteriological water quality criteria under section 304(a) of the Clean Water Act (CWA). Both the current and proposed revised criteria primarily address water quality standards for "primary contact" recreational uses and do not significantly address "secondary contact" recreational uses. Primary contact recreation is typically defined as water-based recreational activities that could be expected to result in the ingestion of or immersion in water such as swimming, water skiing, or surfing. Secondary contact recreation is typically defined as water-based recreational activities where contact with the water is either incidental or accidental, and the probability of ingesting appreciable quantities of water is minimal.

Current EPA policy allows States, tribes and territories to adopt bacteriological criteria for secondary contact uses that are less stringent than criteria for primary contact uses.

The justification for less stringent secondary contact criteria is based on the assumption that secondary contact activities are associated with exposure to fewer pathogenic organisms. It is believed that a higher concentration of pathogens in water is counterbalanced by a lower potential exposure to those pathogens, resulting in the same risk of illness associated with primary recreational activities. However, the potential for pathogen exposure during different recreational activities is not well characterized, and there is currently no scientific consensus on whether or not they are in fact associated with different risks of illness (differential risk).

Although there is a body of scientific literature addressing the risk of illness associated with various water-based recreational activities, the relationships between different activities, water quality, and health risks are not well understood. The wide ranges of existing studies often have ambiguous results or support conflicting conclusions. Such ambiguity and/or disagreement may be due to a variety of reasons, including differences in the questions being addressed, differences, biases and/or flaws in the way the studies were design or conducted, differences in interpretation of the study results, or simply due to chance.

The purpose of this Performance Work Statement (PWS) is to examine the evidence for or against differential risk by conducting a systematic review. A systematic review is a specific type of literature review that focuses on a specific research question and tries to identify, appraise, select and synthesize all high quality research evidence relevant to that question. The overall goal of a systematic review is to provide an objective and transparent synthesis of research results that minimizes bias. The systematic review from this PWS will provide an up-to-date, state-of-the-art evaluation of the current scientific knowledge of the health risks associated with different water-based recreational activities in water contaminated by fecal material. The results and conclusions of the systematic review will be used to inform EPA policies and decisions associated with recreational water quality standards for the protection of public health.

### **Performance Work Statement (PWS):**

The scope of work in this PWS will fall under the following tasks:

#### Task 1 Kickoff meeting, work plan, quality assurance, and monthly progress reports

##### *Task Area 1.1. Introductory ("Kick-Off") Conference Call*

The contractor shall participate in a kickoff meeting with the EPA WAM and EPA staff designated by the EPA WAM via conference call within five (5) days of receipt of the work assignment (WA). The purpose of the kickoff meeting is to discuss and clarify expectations, answer any questions, identify and resolve any potential problems, and to discuss the contractor's proposed schedule to meet task

area deadlines. The contractor shall provide notes from the Kickoff meeting to the EPA WAM within two (2) business days of the meeting.

- Deliverable – Notes from conference call.
- Deadline – fifteen (15) calendar days following the receipt of the WA.

#### Task Area 1.2. Work plan

The contractor shall develop a work plan to address all tasks in the performance work statement (PWS). The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If one or more subcontractor(s) are proposed and they are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. The number and professional level of hours charged and total dollars for each task will be provided. Other costs greater than \$100.00 shall be itemized.

- Deliverable – Work plan.
- Deadline – fifteen (15) calendar days following introductory meeting.

#### *Task Area 1.3. Quality assurance*

Tasks 2 and 3 in this work assignment require the use of secondary data. Consistent with the Agency's quality assurance (QA) requirements, the contractor shall develop a quality assurance project plan (QAPP) to assure the quality of the secondary data or any other types of data used under this PWS. The QAPP must be approved by the EPA WAM before activities using secondary data begin.

The project specific quality assurance requirements shall be addressed in the work plan and monthly progress reports and should follow Attachment 1 entitled: "QAPP requirements for projects using secondary data." The work plan shall explain when the QAPP will be submitted on the basis of the specific data requirements for the work assignment. All projects that involve secondary data must have an approved QAPP before work begins. See Attachment 1.

In addition to the developing a project-specific QAPP, the contractor shall specify the quality assurance (QA) and quality control (QC) procedures that will be implemented in the systematic review within the systematic review protocol to be developed as specified in Task Area 2.2. The systematic review protocol shall include all QA/QC procedures that will be followed when subsequently performing the systematic review as described in Task Area 2.4.

Upon completion of the systematic review, the contractor shall complete the EPA Office of Water Information Quality Guidelines checklist and supporting narrative. See Attachment 2.

- Deliverable – Project-specific QAPP.
- Deadline – seven (7) calendar days following approval of the Work Plan.
- Deliverable – Completed Information Quality Guidelines checklist
- Deadline – seven (7) calendar days following technical direction from the EPA WAM.

#### *Task Area 1.4. Monthly Progress Reports*

The contractor shall provide progress and financial reports to the EPA WAM each month. The contractor shall also provide any information related to the execution of this PWS when ever requested by the EPA WAM at any time. The progress report shall indicate, in a separate QA/QC section, whether QA/QC issues have been identified and how they will be resolved. If significant QA/QC issues are encountered, the contractor shall contact the EPA WAM immediately to discuss the issue. If work ceases because of QA/QC issues, the contractor shall not resume work until receiving written approval from the EPA WAM. Monthly financial reports shall at minimum include a table with the invoice LOE and costs for each task and task area in this PWS.

### Task 2 Develop a systematic review of the scientific evidence related to differential risk of illness with different water-based recreational activities.

#### *Task Area 2.1. Summarize methods, procedures, and approaches for conducting systematic reviews.*

Before beginning a systematic review, a review protocol must be developed. The purpose of the review protocol is to clearly describe the methods, procedures, and approaches that will be used to perform the systematic review before the review is conducted. The contractor shall develop a review protocol as described in Task Area 2.2 below. Before the contractor begins work on the review protocol itself, however, the contractor shall develop a short, concise report that summarizes established methods, procedures, and approaches for conducting systematic reviews. In addition, the contractor shall also specify in the Methods Report which methods, procedures and approaches are expected to be utilized in the systematic review protocol that will be developed and the reasons why.

The contractor shall attempt to use established, state-of-the-art systematic review methods, procedures, and approaches in the systematic review protocol whenever possible and appropriate. If the contractor plans to deviate from established,

state-of-the-art methods, procedures or approaches, the contractor shall identify those methods, procedures, and approaches, describe how and why the protocol will deviate from them, and identify the potential impacts on the goals and objectives of the systematic review.

The contractor shall work closely with the EPA WAM during development of the Methods Report and be available for telephone and conference calls as needed. The final Methods Report shall be well written, organized thoughtfully, concise, grammatically correct, have no spelling errors, and academically rigorous. The contractor shall not begin developing the systematic review protocol itself until the final Methods Report is approved and the contractor receives written instructions by the EPA WAM to do so.

- Deliverable Systematic review Methods Report.
- Deadline -thirty (30) days after approval of the Work Plan by the EPA WAM.

*Task Area 2.2. Develop a systematic review protocol.*

The contractor shall develop a systematic review protocol that reflects current state-of-the-art methods and procedures for conducting systematic reviews, and reflects the general plan outlined in the systematic review Methods Report developed in Task Area 2.1. If, after beginning work on the review protocol itself, the contractor believes the review protocol may need to deviate from the planned methods, procedures, or approaches outlined in the Methods Report, the contractor shall identify those methods, procedures, or approaches, describe how and why the protocol should deviate from them, and identify how such a deviation may potentially impact the goals and objectives of the systematic review.

The review protocol shall be developed in close collaboration with the EPA WAM and other EPA staff designated by the EPA WAM. The contractor shall not begin the review itself until the review protocol has been fully developed and approved by the EPA WAM. At a minimum, the review protocol shall address the following key areas:

Scientific questions to be addressed. The review protocol shall clearly describe the scientific question(s) to be addressed by the review, and how the answers to those questions may provide meaningful information to inform EPA decision-making about primary versus secondary contact criteria and designated uses. The review questions shall be developed in close consultation with the EPA WAM, and be stated clearly and precisely in the review protocol. Once the final scientific questions are determined, the sole purpose of the systematic review shall be to

address only those questions. Under no circumstances shall the systematic review deviate from addressing the established scientific questions without written approval from the EPA WAM.

Background. The review protocol shall have a background section that clearly communicates the key contextual factors and conceptual issues relevant to the review questions. It should explain why the review is required and provide the rationale underpinning the inclusion criteria and the focus of the review questions.

Search strategy. The review protocol shall specify the search strategy that will be used to identify relevant studies that could potentially be included in the review. The contractor shall clearly and transparently describe all steps in the search strategy so that the search results can be reliably reproduced. These details include but are not limited to specifying the databases and additional sources that will be searched and the search terms to be used. Provisions for repeating the searches during the review process and details about how the contractor will manage references shall also be specified.

Inclusion criteria. The review protocol shall describe the criteria for selecting studies that will be included in the review. Factors to consider include population, interventions, comparators, outcomes, and study design. To avoid publication bias, the inclusion criteria shall consider all relevant studies regardless of publication status, including but not limited to peer-reviewed journals, reports, book chapters, conference abstracts, theses, informal reports, and unpublished studies. Studies in any language shall be considered to avoid language bias. If translation of all relevant studies is not feasible, the inclusion criteria shall describe how non-English studies will be addressed in the review.

Study selection. The contractor shall specify in the review protocol the process by which decisions on the selection of studies will be made. Study selection is usually conducted in two stages: an initial screening of titles and abstracts against the inclusion criteria to identify potentially relevant papers, followed by complete screening of papers identified as possibly relevant in the initial screening. The review protocol shall clearly and fully describe the processes that will be used for both stages of study selection. The contractor shall also specify the number of researchers who will screen titles and abstracts and then full papers, and the method for resolving disagreements about study eligibility.

Data abstraction. To the extent possible, the review protocol shall describe the information that will be extracted from studies identified for inclusion in the review. The review protocol shall clearly state the procedures expected to be used for data extraction, including the number of researchers who will extract the data and how discrepancies will be resolved. The protocol shall also specify whether authors of primary studies will be contacted to provide missing or additional data.

If non-English language papers are to be included, translation arrangements will also be specified.

Quality assessment. The protocol shall provide details of the method of study appraisal to be used, including examples of the specific quality criteria. The review protocol shall specify the process for appraising study quality, and the process for weighting studies on the basis of their appraised quality. The review protocol shall also specify how disagreements among study appraisers will be resolved.

Data Synthesis. To the extent possible, the protocol shall specify the strategy for data synthesis. The protocol shall describe the conditions necessary to perform a meta-analysis and how the meta-analysis will be conducted. To the extent possible, the protocol shall describe how heterogeneity will be explored and quantified, and whether a fixed or random-effects model or both will be used and why. The protocol shall also specify the outcomes of interest and what effect measures will be used. The protocol shall describe any planned subgroup or sensitivity analyses or investigation of publication bias and the reasons why. An approach to conducting narrative synthesis shall also be developed and described. If any of the above analyses are not planned, justification for not performing them shall be provided.

QA/QC. The contractor shall incorporate into the review protocol all QA/QC procedures that will be followed while conducting the systematic review. These QA/QC procedures shall be specified within the relevant areas of the review protocol so that the QA/QC procedures to be followed are readily apparent during performance of each stage of the systematic review process.

- Deliverable -- Systematic review protocol.
- Deadline – sixty (60) days after the EPA WAM approves the Methods Report. The WAM will provide the contractor with written instructions to begin work on the review protocol.

*Task Area 2.3. Revise the review protocol in response to possible peer review comments.*

After the systematic review protocol has been approved by the EPA WAM, the EPA WAM may decide that a peer review of the protocol by independent experts outside the EPA is needed. Should the EPA WAM decide that an external peer review is necessary, the contractor shall provide assistance and advice in developing the charge for the peer review and in interpreting the peer review comments. Should the EPA WAM decide that the review protocol needs to be revised in response to an external peer review, the contractor shall revise the

review protocol in accordance with the technical direction provided by the EPA WAM. The contractor shall adhere to the same standards of quality as when initially developing the review protocol as specified in Task Area 2.2. Revisions shall be performed in close collaboration with the EPA WAM and other EPA staff designated by the EPA WAM. The contractor shall not begin the review itself until the review protocol has been finalized and the contractor receives written instructions to do so by the EPA WAM.

- Deliverable – Revised review protocol.
- Deadline – thirty (30) days after receiving peer review comments.

*Task Area 2.4. Conduct the systematic review.*

Upon completion of the final review protocol and receiving written instructions by the EPA WAM, the contractor shall conduct the systematic review as specified in the review protocol. During the screening phase, the contractor shall inform the EPA WAM of the results of initial screening process before beginning full screening of potentially relevant papers. When performing the systematic review, the contractor shall strictly adhere to the review protocol and shall not deviate from it without explicit written permission from the EPA WAM.

Although one objective of the systematic review is to strictly adhere to the review protocol once finalized, modification of the finalized review protocol may be appropriate in some circumstances such as when a clearer understanding of the review question(s) becomes apparent, or when initial screening of papers using the specified eligibility criteria results in too few or too many papers. If, after initial consideration of the studies being reviewed, it becomes apparent that a change in direction may be required, the contractor shall immediately cease review activities and notify the EPA WAM. If the EPA WAM determines that protocol modifications are needed, the contractor shall modify the protocol in consultation with the EPA WAM. The contractor shall not resume review activities until the final modified review protocol is reviewed and approved by the EPA WAM and the contractor receives written instructions to resume review activities. Protocol modifications shall be clearly and fully documented in a protocol addendum and in the final report of the review findings. This documentation shall include a clear description of the differences between the initial and amended protocol, and the implications of the modification on the review findings. **Under no circumstances shall the protocol be modified or the review altered because of awareness of the results of individual studies.**

Throughout the review process, the contractor shall provide progress reports to

the EPA WAM. The contractor shall also provide electronic copies of all documents that were screened during the study selection process or used in the systematic review. A database of complete document citations along with the file name of the electronic copy shall also be provided to the EPA WAM as an Endnote database or another electronic format that can easily be imported into Endnote.

At the conclusion of the systematic review, the contractor shall provide a brief report outlining the results of the review. The report shall be well written, organized thoughtfully, concise, grammatically correct, have no spelling errors, academically rigorous, contain high quality tables and figures if needed, and formatted so that it can serve as the foundation for developing a manuscript to be submitted for publication in a high-quality peer-reviewed journal.

- Deliverable -- Report on review results.
- Deadline ninety (90) days after receiving instructions from the EPA WAM to begin the systematic review.

*Task Area 2.5. Develop one or more manuscripts for publication of the systematic review.*

At the conclusion of the systematic review, the contractor shall develop one or more manuscripts for publication of the systematic review. The manuscript(s) shall be developed in close consultation with the EPA WAM with the goal of publishing the systematic review in a high quality, high impact, peer-reviewed journal. The manuscript(s) shall be organized thoughtfully, written concisely, grammatically correct, academically rigorous, contain high quality tables and figures when appropriate, and formatted for the journal being targeted. The manuscript(s) shall be developed in a way that allows reformatting for submission to other journals if the need arises. The contractor shall revise the manuscript(s) as instructed by the EPA WAM in response to reviewer comments, and develop written responses to reviewer comments for submission to the journal editor. The contractor shall conform to the same standards of quality when revising the manuscript(s) as specified above for initially developing the manuscript(s). The contractor shall also prepare the Information Quality Guidelines Checklist necessary for products that EPA disseminates to the public under EPA's Information Quality Guidelines.

- Deliverable – Draft manuscript.
- Deadline – thirty (30) days after receiving instructions from the EPA WAM to begin writing manuscript.

### Task Area 3 - General Project Support

*Task Area 3.1. Prepare briefing materials and other supporting documents pertaining to the systematic review.*

Briefing materials and other supporting documents will be needed during the systematic review development process and after the review is published. The contractor shall aid in the development of any materials or presentations for these purposes. This may include but is not limited to preparing interim project updates and other materials for internal and external audiences as requested by the EPA WAM, briefing documents, PowerPoint presentations, and other supporting documents as needed. The contractor may be requested by the EPA WAM to participate in and/or conduct briefings or participate in seminars or talks related to the systematic review.

- Deliverable -- Requested materials and supporting documents.
- Deadline – As agreed upon by the WAM and contractor

*Task Area 3.2. Support options development and analyses for potential changes to EPA policies related to bacteriological water quality standards.*

As the results and conclusions of the systematic review become clear, the EPA may want to consider alternative policies related to bacteriological water quality standards. The contractor shall aid in the development of potential alternative policy options. These activities may include but are not limited to performing additional research and analysis of existing scientific data and information, analysis of the potential public health outcomes resulting from policy modifications, and the analysis of water quality standard implementation implications associated with the adoption of alternative bacteriological water quality standards. The contractor may be requested to participate in and/or conduct briefings or other presentations related to this work.

- Deliverable – Requested materials.
- Deadline – As agreed upon by the WAM and contractor
- 

#### **Travel:**

Travel may be needed as deemed necessary by the EPA WAM. No contractor travel outside of the Washington, D.C. metro area is required.

**Conferences:**

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA PO as needed and provided to the Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the EPA PO.

**Knowledge and Skills Required:**

The contractor shall have the necessary scientific knowledge and expertise to develop the aforementioned materials in this PWS that are high quality and use state-of-the-art methods. Specifically, the contractor shall have experience designing, performing, and publishing primary scientific research evaluating the health effects of environmental pollution, as well as experience designing, performing, and publishing systematic- and meta-analyses of such studies. The contractor shall have expertise in epidemiological studies that evaluate microbiological water pollution using fecal indicator organisms. The contractor shall be proficient in advanced state-of-the-art statistical methods typically used to analyze epidemiological studies and perform meta-analyses. The contractor should also be competent in analytical methods used to monitor microbial water pollution (including molecular techniques), the determination of human exposure to environmental contaminant sources, and disease endpoints related to microbial exposure through contact with water.

**General Requirements of the Work Assignment and Schedule:**Due Dates

The contractor shall mutually acceptable due dates with EPA WAM. The contractor shall notify the EPA WAM in advance, if a due date will not be met and negotiate a mutually acceptable revised due date.

Delays

The contractor shall provide sufficient qualified man-power to ensure there are no avoidable delays. If a delay outside the control of the contractor is unavoidable, the contractor shall immediately notify the EPA WAM and negotiate a mutually acceptable revised schedule.

Draft Documents

The contractor shall submit draft or interim work products requested by the EPA WAM. Draft or interim work products shall be prepared in an electronic format compatible with

Microsoft Office 2007 or Endnote X. The EPA WAM will provide the contractor with comments on draft work products in electronic format. Work products shall be deemed draft until designated as final by the EPA WAM.

Final Documents

The contractor shall submit final documents electronically to the EPA WAM.

## **ATTACHMENT 1**

### **QAPP Requirement for Projects Using Secondary Data**

A project involving secondary data gathers and uses existing data for purposes other than those for which they may have been originally collected. These secondary data may be obtained from many sources including literature, industry, computerized databases and information systems, and computerized or mathematical models of environmental processes. For projects that use secondary data, a QAPP shall be prepared that include the requirements identified below. If primary data will also be generated as part of the project, then the information below can be incorporated into the associated QAPP to address the secondary data. The following requirements should be addressed as applicable.

#### **Section 1. Project Objectives, Organization, and Responsibilities**

- 1.1 The purpose of study shall be clearly stated.
- 1.2 Project objectives shall be clearly stated.
- 1.3 The secondary data needed to satisfy the project objectives shall be identified. Requirements relating to the type of data, the age of data, geographical representation, temporal representation, and technological representation, as applicable, shall be specified.
- 1.4 The planned approach for evaluating project objectives, including formulas, units, definitions of terms, and statistical or other types of data analysis. Assumptions and or recommendations based on the data analysis shall also be included if applicable.
- 1.5 Responsibilities of all project participants shall be identified, meaning that key personnel and their organizations shall be identified, along with the designation of responsibilities for planning, coordination, data gathering, data analysis, report preparation, and quality assurance, as applicable.

#### **Section 2. Sources of Secondary Data**

- 2.1 The source(s) of the secondary data must be specified.
- 2.2 The rationale for selecting the source(s) identified shall be discussed.
- 2.3 The sources of the secondary data will be identified in any project deliverable.

#### **Section 3. Quality of Secondary Data**

- 3.1 Quality requirements of the secondary data must be specified. These requirements must be appropriate for their intended use. Accuracy, precision, representativeness, completeness, and comparability need to be addressed, if

applicable. (If appropriate, a related QAPP containing this information can be referenced.)

- 3.2 The procedures for determining the quality of the secondary data shall be described.
- 3.3 If no quality requirements exist, this shall be stated in the QAPP. If no quality requirements exist or if the quality of the secondary data will not be evaluated by EPA, the QAPP shall require that a disclaimer be added to any project deliverable to indicate that the quality of the secondary data has not been evaluated by EPA for this specific application. The wording for the disclaimer shall be defined.

#### **Section 4. Data Reporting, Data Reduction, and Data Validation**

- 4.1 Data reduction procedures specific to the project shall be described, including calculations and equations.
- 4.2 The data validation procedures used to ensure the reporting of accurate project data shall be described.
- 4.3 The expected product document that will be prepared shall be specified (*e.g.*, journal article, final report, *etc.*).

## ATTACHMENT 2

### Office of Water

#### Information Quality Guidelines:

#### Pre-Dissemination Review Guidance and Checklists

version 2.2 (January 10, 2003)

#### BACKGROUND

In order to comply with Section 515 of the Treasury and General Government Appropriations Act for FY 2002 (Public Law 106-554), the Office of Management and Budget developed guidelines that “provide policy and procedural guidance for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies.”

In response to OMB’s guidelines (FRL-7157-8, March 2002), EPA developed the *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* (The Guidelines), which contains EPA’s policy and procedural guidance for ensuring and maximizing the quality of the information we disseminate. “Quality” refers to objectivity, integrity, and utility.

The Guidelines also:

- outline administrative mechanisms for EPA pre-dissemination review of information products
- enable affected persons to file complaints regarding disseminated information that they believe to be noncompliant with EPA’s Guidelines.

Implementation began *October 1, 2002*.

For more information, visit <http://www.epa.gov/oei/qualityguidelines/>

In order to ensure that information meets The Guidelines, the following guidance and checklists should be used prior to dissemination.

#### OVERVIEW

- What information is covered under The Guidelines?

version 2.2 (January 10, 2003)

- Is your organization in compliance with EPA's existing Quality System and Office of Water's Quality Management Plan?
- What type of information do I have?
- Do additional guidelines apply for externally gathered data?
- Checklists for Pre-Dissemination Review
- What are Requests for Correction and Requests for Reconsideration, and how does OW respond to them?

## **WHAT INFORMATION IS COVERED UNDER THE GUIDELINES?**

These guidelines apply only to *information* EPA *disseminates* to the public.

### What DO The Guidelines cover?

- EPA prepares the information and distributes it to support or represent EPA's viewpoint, or to formulate or support a regulation, guidance, or other Agency decision or position.
- EPA distributes information prepared or submitted by an outside party in a manner that reasonably suggests that EPA endorses or agrees with it.
- EPA reviews and comments on information distributed by an outside party in a manner that indicates EPA is endorsing it, directs the outside party to disseminate it on EPA's behalf, or otherwise adopts or endorses it.

### What DON'T The Guidelines cover?

- Distribution of information for government employees
- EPA response to FOIA, FACA, or similar legislation
- Correspondence directed to individuals or persons
- Information presented solely to Congress
- Ephemeral information (press releases, fact sheets, press conferences)
- Background information (published articles distributed by libraries, or other non-EPA endorsed distributions)
- Information distributed by recipients of EPA grants, contracts, or cooperative agreements *unless* EPA adopts or endorses the information
- Information in public filings, including information submitted to EPA, either voluntarily or under mandates/requirements
- Distribution of information in judicial cases or administrative adjudication

## **IS YOUR ORGANIZATION IN COMPLIANCE WITH EPA'S EXISTING QUALITY SYSTEM AND OFFICE OF WATER'S QUALITY MANAGEMENT PLAN?**

Many of EPA's current quality assurance practices fulfill much of EPA's Information Quality Guidelines. Examples of these policies are: Quality System, Peer Review, Action Development

Process, Integrated Error Correction Process, Information Resources Management Manual, Risk Characterization Policy and Handbook, Program-Specific Policies, and EPA's Commitment to Continuous Improvement. EPA information disseminated to the public must meet EPA's already existing Quality System and other related policies. The Quality System utilizes a graded approach to establish quality criteria that are appropriate for the intended use of the information and the resources available. (The Quality System can be found in EPA Order 5360.1 A2, "Policy and Program Requirements for the Mandatory Agency-wide Quality System" and in the "EPA Quality Manual".)

The Quality System requires Agency organizations to:

- Assign a quality assurance manager
- Develop a Quality Management Plan
- Conduct an annual assessment of the organization's quality system
- Use a systematic planning process to develop acceptance or performance criteria prior to the initiation of all projects that involve environmental information collection and/or use
- Develop Quality Assurance Project Plans for all applicable projects and tasks involving environmental data
- Conduct an assessment of existing data, when used to support Agency decisions or other secondary purposes, to verify accuracy
- Implement all Agency-wide Quality System components in all applicable EPA-funded extramural agreements
- Provide appropriate training for all levels of management and staff

The Office of Water implements EPA's Quality System through its Quality Management Plan, approved by OEI in September 2001. Please refer to this document to ensure that the information you are disseminating complies with Office of Water quality assurance policies.

### **WHAT TYPE OF INFORMATION DO I HAVE?**

Different quality standards apply to influential information, influential scientific risk assessment information, and non-influential information. The definitions of these three types of information are:

Influential: when the Agency can reasonably determine that dissemination of the information will have a clear and substantial impact on important public policies or private sector decisions. These include OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis. Influential information must meet a higher standard of quality: "reproducibility".

Reproducibility: providing enough information to allow the public to reproduce our analyses

Influential Scientific Risk Assessment: applies to all dissemination of information regarding human health, environmental, or safety risk assessments, *except* those conducted under the Safe Drinking Water Act, which will adhere to SDWA principles. Information is required to be accurate, reliable, and unbiased; it should also be comprehensive, informative, and understandable. The quality standard is “objectivity,” and uses the following principles:

- Information is accurate, reliable, and unbiased. This involves:
  - Best available science, which utilizes sound and objective scientific practices, and peer review when available
  - Data collection by accepted methods
- Presentation of information is consistent with the purpose of the information, is comprehensive, informative, and understandable. This means specifying:
  - each population addressed by the risk
  - expected risk or central estimate
  - upper-bound and lower-bound estimate of risk
  - significant uncertainties identified
  - peer reviewed studies known to the Administrator

Non-Influential: standard of quality is “transparency.”

Transparency: the public can understand how conclusions were obtained on the information

### **DO ADDITIONAL GUIDELINES APPLY FOR EXTERNALLY GATHERED DATA?**

Most external environmental data is within the scope of the Quality System. This includes literature, industry surveys, compilations from computerized databases and information systems, and results from computerized or mathematical models of environmental processes and conditions.

Regarding voluntarily submitted information, EPA will continue to work with States and other governments, the scientific and technical community, and other interested information providers to develop and publish criteria the EPA would use to assess this type of information.

**Depending on your information, you need only fill out ONE of the following three checklists. Please forward the checklists to OW’s Information Quality Guidelines Officer (currently Leo Gueriguian, 564-0388) for approval and signature. The checklist must then be signed by your Division Director, and a copy sent to your Quality Assurance Officer. Please also note that outside entities may file Requests for Correction (i.e. complaints) to EPA, citing non-compliance with EPA’s Information Quality Guidelines.**

***\*\*Note: OGWDW staff should send their completed checklists directly to their Division Directors. They should work with the OW IQ Guidelines Officer, as their projects and checklists are being developed.***

**Office of Water**

**Information Quality Guidelines Checklist for**

***Influential Information***

Influential Information has or will have a clear and substantial impact on important public policies or private sector decisions. (Includes OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis.)

- The information to be disseminated is covered under The Guidelines.
- The information is in compliance with EPA's Quality System and other related policies.
- The information is in compliance with Office of Water's Quality Management Plan.
- The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
  - Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
  - Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
  - Utility: the information is useful to the intended users.
- The information meets "reproducibility" standard.  
The information and its accompanying documentation has a higher degree of transparency regarding the following:
  - The source of the data used
  - The various assumptions employed
  - The analytic methods applied
  - The statistical procedures employed

\_\_\_\_\_  
Division Director's Signature & Date

\_\_\_\_\_  
IQG Officer for OW Signature & Date

(Officer signature Not needed for OGWDW staff)

\*\*If your information does not comply with any of these items, please attach brief explanation of any omissions. Please forward a copy of this document to your office's Quality Assurance Officer.

## Office of Water

### Information Quality Guidelines Checklist for

#### *Influential Risk Assessment Information*

Influential Scientific Risk Assessment Information has or will have a clear and substantial impact on important public policies or private sector decisions. (Includes OMB economically significant actions, peer reviewed documents, top Agency policy documents, and other actions on a case-by-case basis.)

- The information to be disseminated is covered under The Guidelines.
- The information is in compliance with EPA's Quality System and other related policies.
- The information is in compliance with Office of Water's Quality Management Plan.
- The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
  - Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
  - Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
  - Utility: the information is useful to the intended users.
- The information meets "objectivity" standard.
  - The information is accurate, reliable, and unbiased:
    - best available science and supporting studies conducted using sound and objective scientific practices, including peer reviewed studies
    - data were collected by accepted methods or best available methods (if the method's reliability nature of the decision justifies the use of the data)
  - Presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, is comprehensive, informative, and understandable. Each of the following must be specified:
    - each population addressed by the risk or each risk assessment endpoint addressed by any estimate of applicable ecological risk
    - expected risk or central estimate for the specific populations affected or the ecological assessment endpoints
    - upper-bound and lower-bound estimate of risk
    - significant uncertainties identified, and studies that would assist in resolving uncertainties

-peer reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data

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Division Director's Signature & Date

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IQG Officer for OW Signature & Date

(Officer signature Not needed for OGWDW staff)

\*\*If your information does not comply with any of these items, please attach brief explanation of any omissions. Please forward a copy of this document to your office's Quality Assurance Officer.

**Office of Water**

**Information Quality Guidelines Checklist for**

***Non-Influential Information***

- The information to be disseminated is covered under The Guidelines.
- The information is in compliance with EPA's Quality System and other related policies.
- The information is in compliance with Office of Water's Quality Management Plan.
- The information is consistent with the OMB definition of "quality," meaning the information has a high level of objectivity, utility, and integrity.
  - Objectivity: information is presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased.
  - Integrity: the information cannot be compromised through corruption or falsification because it is secure from unauthorized access or revision.
  - Utility: the information is useful to the intended users.
  
- Meets "transparency" quality standard: the public can understand the source of the information and how conclusions were reached on the information.

\_\_\_\_\_  
Division Director's Signature & Date

\_\_\_\_\_  
IQG Officer for OW Signature & Date

(Officer signature Not needed for OGWDW staff)

\*\*If your information does not comply with any of these items, please attach brief explanation of any omissions. Please forward a copy of this document to your office's Quality Assurance Officer.

## Helpful information for Completing OW IQG Checklists

- (1) **The information is in compliance with EPA's Quality System and other related policies.**

Of specific interest:

### **EPA INFORMATION QUALITY GUIDELINES**

▪ **EPA PEER REVIEW POLICY:**

**Is this product a major product under the Agency's peer Review Policy?**

Described in the *Science Policy Council Peer Review Handbook*, the EPA Peer Review Policy regards major scientific and technical work products as those that have a major impact, involve precedential, novel, and/or controversial issues, or the Agency has a legal and/or statutory obligation to conduct a peer review.

**If so, has it undergone appropriate peer review?** Or, is your AA-ship or Region able to articulate why peer review was not conducted?

▪ **EPA QUALITY SYSTEM:**

Does this product present or use environmental data?

- If so, did this product complete a **Quality Assurance Project Plan (QAPP)** or equivalent document(s) for all applicable projects and tasks involving environmental data?
- Did this product conduct **an assessment of existing data**, when used to support Agency decisions or other secondary purposes, to verify that they are of sufficient quantity and adequate quality for their intended use?

▪ **EPA RISK CHARACTERIZATION POLICY AND HANDBOOK, AND OTHER RISK POLICIES**

- The EPA Risk Characterization Policy and Handbook provide guidance for risk characterization that is designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk. The Policy calls for a transparent process and products that are clear, consistent and reasonable. The Handbook is designed to provide risk assessors, risk managers, and other decision-makers an understanding of the goals and principles of risk characterization.

- (2) **Ensuring transparency:**

Currently, the EPA IQGs do not describe in great detail how EPA intends to ensure transparency and what exactly transparency consists of but rather state in a general sense EPA's renewed commitment to information transparency for all information products.

The Office of Environmental Information recommends inclusion of the following 5 basic elements in an information product that is being released to the public. This information should be easy to find within a product.

**1. Purpose** — information products should clearly state the purpose of the product itself. The product should also include a discussion of the intended audience, why the product was created, and an overview of the analysis behind and/or information within the product.

**2. Explanation of Potential Uses** — information products should provide explanations of how the various types of information and/or analyses presented in the product can be used. Each information product should clearly convey why the product was developed (i.e., what its intended use is). This will help users ascertain product quality as it suits their own needs.

**3. Product content: Inputs, Methodology, and Outputs** — the product should clearly explain to product users the sources of data used to develop the information product (inputs), the scope of the analysis and how the information was put together (methodology), and the information that is made uniquely available through the information product (outputs).

**4. Product Limitations and Caveats** — a product should clearly state the strengths and weaknesses of the information product, and the accuracy of the source data used for its intended use. In addition, the metadata should also discuss the implications of data quality on the product itself. Furthermore, this where a product developer should be informing the user of the origins of the data and the quality considerations associated with secondary use. The product should describe the difference between why the data was initially collected and how such quality considerations are accommodated in the most recent use by EPA in this new product.

**5. Contact information** — the information product should explain users with basic contact information. Products should let users know who is responsible for the product and whom they can contact to obtain more information and/or obtain answers to questions they may have on the product or any analyses presented in the product. This is also important in case the user wishes to submit a Request for Correction or later a Request for Reconsideration. The user should be able to tell which Program and/or Region the product came from.

## **WHAT ARE REQUESTS FOR CORRECTION AND REQUESTS FOR RECONSIDERATION, AND HOW DOES OW RESPOND TO THEM?**

The public and outside entities may send complaints to the Office of Environmental Information, stating that EPA information does not comply with OMB's or EPA's Information Quality Guidelines. These complaints are called Requests for Corrections (RFC). These requests should include contact information of the requester, a description of the EPA information in question, an explanation of how the information does not comply with the Guidelines, a recommendation for corrective action, and an explanation of how the alleged error affects or how a correction would benefit the requester.

When an RFC is received by OEI, they will send the RFC to OW, if the information in question is under our jurisdiction. OEI will send the RFC to OW's IQ Guidelines Officer, currently Leo Gueriguian, who will then prepare a controlled correspondence to the Office, who has disseminated the information. In addition, a memo will be sent to managers informing them of the Request. The OW Program Office will be responsible for crafting a response. If the response is an approval, the Office Director may sign the response and send it to the requester of the correction. In addition, a copy should be sent to OW's IQ Guidelines Officer. If the response is a disapproval, the response should be sent to the Assistant Administrator for concurrence on the decision. After AA concurrence, the response will be sent to the outside requester, with a copy to OW's IQ Guidelines Officer. OW has 90 days to respond to requester. If additional time is needed for making a decision on an RFC, OW must send requester a letter informing them that OW is currently processing their request. Please see OW RFC Process Diagram.

If the requester does not agree with the decision by EPA, they have the right to an appeal, officially called a Request for Reconsideration (RFR). The RFR is sent to OEI, who contacts OW. The decision on RFRs are NOT made by OW, but by an executive panel consisting of EPA's Chief Information Officer, Science Advisor, and Economics Advisor. OW will be consulted, prior to any decision. The OW IQ Guidelines Officer will contact all managers and staff affected by the RFR and convene a meeting to discuss OW's stance on the RFR.

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-10

Other  Amendment Number:

Contract Number  
EP-C-11-005

Contract Period 01/01/2011 To 12/31/2012

Title of Work Assignment/SF Site Name

Base Option Period Number 1

Water Quality Standards for Pa

Contractor  
ICF INCORPORATED, L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, and 3.4

Purpose:  Work Assignment  Work Assignment Close-Out  
 Work Assignment Amendment  Incremental Funding  
 Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

SFO (Max 2)

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012 Cost/Fee: \$0.00 LOE:

This Action: \$195,857.44

Total: \$195,857.44

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 09/20/2012 Cost/Fee: \$200,622.00 LOE: 1,850

Cumulative Approved: Cost/Fee: \$200,622.00 LOE: 1,850

Work Assignment Manager Name Gary Russo

Branch/Mail Code:

Phone Number 202-566-1335

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Contracting Official Name Sandra Stargardt-Licis

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

(Signature)

(Date)

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-11

Other  Amendment Number

Contract Number

EP-C-11-005

Contract Period 01/01/2011 To 12/31/2012

Base Option Period Number 1

Title of Work Assignment/SF Site Name

Support for Developing Technic

Contractor

ICF INCORPORATED, I.L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.6

Purpose

Work Assignment

Work Assignment Close-Out

Work Assignment Amendment

Incremental Funding

Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments:

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-65A

SFO (Max 2)

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period

01/01/2011 To 12/31/2012

Cost/Fee:

LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated

Cost/Fee:

LOE:

Cumulative Approved

Cost/Fee

LOE

Work Assignment Manager Name John Ravenscroft

(Signature)

(Date)

Branch/Mail Code:

Phone Number 202-566-1101

FAX Number:

Project Officer Name Shirley Harrison

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Other Agency Official Name Shirley Harrison

(Signature)

(Date)

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

Contracting Official Name Sandra Stargardt-Licis

(Signature)

(Date) 8/28/12

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

Performance Work Statement  
ICF Contract # EP-C-11-005  
Work Assignment #1-11

**Title:** Support for Developing Technical Support Materials (TSM) for Deriving Site-Specific Water Quality Criteria Based on Alternative Health Relationships

**Work Assignment Manager:** John Ravenscroft (Mail Code 4304T)  
Office of Water, Office of Science and Technology  
Health and Ecological Criteria Division  
1200 Pennsylvania Ave, N.W.  
Washington, DC 20460  
Phone (202) 566-1101  
E-mail: [ravenscroft.john@epa.gov](mailto:ravenscroft.john@epa.gov)

**Alternate WAM:** Shamima Akhter (Mail Code 4304T)  
Health and Ecological Criteria Division  
Office of Science and Technology, Office of Water  
1200 Pennsylvania Avenue, NW  
Washington DC, 20460  
Phone: 202-566-1341  
E-mail: [akhter.shamima@epa.gov](mailto:akhter.shamima@epa.gov)

**Period of Performance:** Work Assignment Issuance through December 31, 2012

**\*\*Note:** No CBI data will be needed in the course of this work assignment.

Contractor PWS: 3.1, 3.3, 3.6

**Goal:** The overall goal of this work assignment is to develop implementation guidance for States and Tribes to use in developing site-specific water quality criteria based on alternative human health associations with water quality measures.

**Objectives:**

1. Produce a comprehensive report for internal EPA evaluation detailing the framework, process, and scientific foundation that the intended end users of this information (i.e., States, Tribes, and EPA) can utilize in developing and evaluating a site-specific water quality standards package based on an alternative human health relationship with water quality.
2. Respond to EPA and peer review comments on the report covered in Objective 1.
3. Produce a polished report in response to Objective 2 that the Agency can publish on its website
4. Produce communications materials to accompany reports including: a 1 to 2 page nontechnical synopsis, a technical summary document written in non-academic style for a non-scientific audience, a 'questions and answers' (Q&As) document covering areas of

potential inquiry from nontechnical and technical audiences (both internal and external), and others as determined by the EPA WAM via technical direction.

**Background:** EPA is on track to issue new CWA 304(a) Recreational Water Quality Criteria (RWQC) by December 2012. The science underpinning the new criteria describes human health effects and water quality studies conducted in waters impacted primarily by human sources of fecal contamination. EPA recommended water quality criteria for fecal indicator bacteria based on the epidemiological studies conducted by EPA's Office of Research and Development (ORD). These studies were conducted at a subset of recreational waters impacted by human fecal contamination. While EPA considers these recommended criteria to be scientifically defensible and protective of the use on a national basis, the Agency recognized that certain site-specific conditions exist that would allow alternative, equally protective, criteria to be considered for Water Quality Standards. EPA clarified additional potential approaches to developing site-specific water quality criteria in Section 5 of the draft RWQC published in December 2011. These approaches focused on three main areas: 1) alternative indicators; 2) alternative sources of fecal contamination; and 3) alternative health relationships. This work assignment addresses the alternative health relationship approach.

Generally speaking, the alternative health relationship approach would consist of the development of a site-specific recreational water quality criteria derived from a human health association with water quality that differs from the one EPA has used as the basis for the nationally-applicable 2012 recommendations. EPA has committed to publishing implementation guidance, hereafter termed Technical Support Materials (TSM), for use by States and Tribes who may be interested in pursuing the development of site-specific criteria. This work assignment covers the various aspects needed to develop these TSM, including the collation and development of background and supplemental information needed for the application of this approach in the development of site-specific Water Quality Standards packages to be evaluated by EPA.

**Task Knowledge and Skills Required:** The Contractor shall have expertise in preparing the materials associated with this work assignment and be knowledgeable with the various fields of discipline discussed, including epidemiology, microbial risk assessment, biostatistics, and environmental microbiology. The Contractor shall be familiar with the different programs under the CWA, use of water quality monitoring, determination of human exposure to environmental contaminant sources, and gastrointestinal (or other) disease endpoints, applications of epidemiological data, and other factors associated with needs in recreational water quality and CWA 304(a) criteria development. The Contractor shall also be able to communicate the study outcomes and recreational outbreak data to a non-technical audience.

**Quality Assurance:** The tasks in this work assignment (WA) require the use of secondary data/analyses and fall under the scope of the approved contract-level QAPP. Consistent with the Agency's quality assurance (QA) requirements, the contractor must assure the quality and analyses of the secondary data and other data collected to be used under this work assignment.

The Contractor shall discuss with the EPA WAM if any of the specific work assignment tasks are not readily covered under the approved QAPP. Any additional quality assurance requirements must be addressed in the work plan and monthly progress reports and, if needed, be covered by a WA-specific QAPP supplement, which must be approved by the EPA WAM before activities covered by the additional QA language begin under this work assignment.

### **Task 1: Work plan, monthly progress reports and quality assurance**

#### *Task 1.1: Work plan*

The contractor shall develop a work plan to address all tasks in this work assignment. The work plan shall include a schedule, staffing plan, level of effort (LOE), and cost estimate for each task, the contractor's key assumptions on which staffing plan and budget are based, and qualifications of proposed staff. If a subcontractor(s) is proposed and subcontractors are outside the metropolitan DC area, the contractor shall include information on plans to manage work and contract costs. All P levels, hours and total dollars for each task will be provided and costs greater than \$100.00 shall be itemized in detail. The contractor shall provide their job number with all invoices to facilitate their expediency.

This task also includes monthly progress and financial reports. The monthly progress report shall indicate in a separate QA section, whether significant QA issues have been identified and how they are being resolved. Monthly financial reports must include a table with the invoice LOE and costs delineated by the tasks in this WA. These reports should also indicate an estimate for the next month by task and if any lagging costs are expected. EPA realizes these estimates are just approximate values and is interested in having this information for internal budgeting purposes.

#### *Task 1.2: Information Quality Guidelines*

The Contractor shall ensure the products developed under this work assignment comply with the EPA Information Quality Guidelines and shall complete the Checklist for Influential Information as needed for each deliverable from this work assignment as they may be used in Agency decision-making and/or will be publicly available documents. The EPA WAM will provide the checklist to the Contractor. The Contractor shall provide a memorandum describing how the planned product(s) developed meet EPA's Information Quality Guidelines checklist. As part of that memo, the Contractor shall document the quality assurance procedures it used in developing the deliverables under this Work Assignment. The Contractor shall provide the memo at the time it delivers the Final Summary Report. The Contractor shall have a teleconference with the EPA WAM to discuss the Guidelines and the Contractor's role in completing the checklist..

### **Task 2: General Project Support and Development of TSM Considering Alternative Health Relationships**

EPA is planning to make available guidance to States for consideration in developing site-specific Water Quality Standards (WQS) packages utilizing alternative human health

associations with water quality measures. Task 2 comprises the different facets of the guidance development project and includes project planning, communication strategies, and document preparation.

*Task 2.1. Project planning and management*

The Contractor shall conduct project strategic planning in conjunction with the EPA WAM. The purpose of this subtask will be to develop a comprehensive plan that includes all related tasks and deliverables in the context of the Agency timeline for publishing RWQC and implementation guidance. The plan will also describe how each task or subtask will aid EPA in meeting its goals in regards to the publication of technical support materials in support of criteria implementation.

Deliverables under this subtask will include the preparation of a project plan and schedule, including a graphical representation (e.g., Gantt chart) to aid in discussions with management. Project management coordination between the EPA WAM and the Contractor shall occur for the duration of the work assignment. Regular periodic meetings between the EPA WAM and the Contractor shall occur once the workplan has been approved.

*Task 2.2. Project communication support*

The contractor shall, based on technical direction given by the EPA WAM, provide support in preparing interim project updates and other materials for internal and external audiences. These may include, but are not limited to, short briefing documents and PowerPoint presentations. The Contractor may be requested to participate in briefings and meetings. The Contractor may be requested to prepare reports for communication outside the EPA based on deliverables generated by tasks under this work assignment. The Contractor shall coordinate with the EPA WAM for the proper timing and need for these activities.

Interpretation and meta-analyses of epidemiological evidence are two potential technical areas that will need to be considered in the preparation of the TSM. The Contractor shall anticipate the need to discuss specific topics of a highly technical nature with ORD epidemiologists and also to convey the outcomes of such discussions to a non-technical audience.

*Task 2.3: TSM document development*

The purpose of this task is to develop a guide for use by States and localities for the purposes of deriving site-specific water quality criteria derived from alternative human health relationships to water quality, including information for evaluating the technical basis for the site-specific criteria. This guide should also provide information for EPA, particularly for Regional personnel who are tasked to evaluate State WQS packages. This document shall discuss a process to help States determine if a water body is eligible for the development of site-specific criteria, what information can be used to provide a line of evidence approach for demonstrating human health relationships with water quality, the differing approaches to establishing human health relationships with water quality, a comparison of site-specific health relationships to those used by EPA as a basis for the nationally recommended water quality criteria, a potential epidemiological and Quantitative Microbial Risk Assessment (QMRA) hybrid approach for

demonstrating human health relationships, how to prepare a site-specific water quality standards package, and other topics as needed to be specified by the EPA WAM (and in consultation with HECD's partners in SHPD). The main goal for this deliverable is to produce guidance for use by States in developing microbial WQS that are scientifically defensible, protective of the recreational designated use, and meet EPA standards for consideration and potential approval.

This document should be clear to a potentially non-technical audience on the state of the science for epidemiology and risk assessment. For example, a good discussion will be needed for comparing results from various epidemiological studies conducted with different study designs. The discussion should include what the differences between the study designs are and what impact they have on the potential interpretation of the results, particularly in terms of comparing study results to EPA's recommendations. This type of discussion will be important for evaluating the scientific defensibility and protection of the designated use for any site-specific criteria derived from alternative study designs. The Contractor shall use examples from the peer reviewed literature, where possible, to highlight this discussion.

The draft deliverable for this task (see table below) will need to be peer reviewed by a 3<sup>rd</sup> party. The Contractor shall respond to the peer reviewer comments as directed by the EPA WAM via technical direction in preparation of the final deliverable. The final deliverable shall be Section 508 compliant as specified in the US Rehabilitation Act internet-based publications.

This task will require the Contractor to attend meetings with the EPA WAM and other staff at EPA Headquarters during the period of performance for the purposes of project updates, planning and communication.

All appropriate clearances and approvals required by Agency policy in support of any and all conference related activities and expenses, including support of meetings, conferences, training events, award ceremonies and receptions, shall be obtained by the EPA WAM as needed and provided to the Project Officer and Contracting Officer. Work under conference related activities and expenses shall not occur until this approval is obtained and provided by the PO.

**General Requirements of the Work Assignment and Schedule:**

Due Dates: The Contractor shall provide due dates that are mutually acceptable with the EPA WAM. The Contractor shall notify the EPA WAM in advance, if a due date will not be met and request a revised date.

Delays: The Contractor shall make every effort to ensure there are no Contractor-caused delays. If a delay is inevitable, it is the Contractor's responsibility to notify the EPA WAM at the first sign of said delay. A revised schedule will then be worked out.

Draft Documents: The Contractor may be required to submit draft documents. Draft documents shall be prepared in an electronic format compatible with current Microsoft products. EPA WAM will provide comments on draft submissions prior to submission of final documents.

Final Documents: The Contractor shall submit final documents both electronically and in hardcopy to EPA WAM.

Milestone/Deliverable Table

Task	Task #	Milestones and Due Dates
<b>Task 1: Work plan, monthly progress reports and quality assurance</b>		
Workplan	1.1	Within 15 calendar days of receipt of work assignment
Information Quality Guidelines	1.2	Discuss with EAP WAM within 15 calendar days of receipt of work assignment. IQG checklists due with final deliverable (can be included with QA materials).
<b>Task 2: General Project Support</b>		
Project Planning and Management	2.1	Initial planning meeting to be held within 15 calendar days of receipt of work assignment. Meeting shall update project Gantt chart, goals and objectives statement, and gap analysis due within 2 weeks of initial meeting. Drafts of this deliverable would be expected at the close of the initial meeting. Subsequent meetings to be held roughly every quarter thereafter.
Project Communication Support	2.2	After the workplan approval, throughout the period of performance. Communication materials will be informed by the results and be targeted for different audiences..
Technical Support Materials	2.3	Draft for internal review, 11/15/12 (communication materials included); EPA may have additional comments; 3 <sup>rd</sup> party peer review will take approximately 90 days; Contractor shall coordinate with EPA WAM on the response to comments; Final by 4/30/13 contingent on EPA comments.

EPA

United States Environmental Protection Agency  
Washington, DC 20460

Work Assignment

Work Assignment Number

1-11

Other  Amendment Number:

Contract Number  
22-C-11-005

Contract Period 01/01/2011 to 12/31/2012

Title of Work Assignment/SF Site Name

Base Option Period Number 1

TSM for Air Eith Relationships

Contractor  
COF INCORPORATED, D.L.L.C.

Specify Section and paragraph of Contract SOW

3.1, 3.3, 3.6

Purpose:  Work Assignment  Work Assignment Close Out  
 Work Assignment Amendment  Incremental Funding  
 Work Plan Approval

Period of Performance

From 01/01/2012 To 12/31/2012

Comments

Superfund

Accounting and Appropriations Data

Non-Superfund

Note: To report additional accounting and appropriations data use EPA Form 1900-69A.

SFO (Max 2)

Line	DCN (Max 6)	Budget/FY (Max 4)	Appropriation Code (Max 6)	Budget Org/Code (Max 7)	Program Element (Max 9)	Object Class (Max 4)	Amount (Dollars)	(Cents)	Site/Project (Max 8)	Cost Org/Code (Max 7)
1										
2										
3										
4										
5										

Authorized Work Assignment Ceiling

Contract Period: 01/01/2011 To 12/31/2012 Cost/Fee: \$0.00 LOE:

This Action:

Total:

Work Plan / Cost Estimate Approvals

Contractor WP Dated: 09/13/2012 Cost/Fee: \$79,947.00 LOE: 620

Cumulative Approved Cost/Fee: \$79,947.00 LOE: 620

Work Assignment Manager Name John Ravenscroft

Branch/Mail Code:

Phone Number 202-566-1101

FAX Number:

(Signature)

(Date)

Project Officer Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Other Agency Official Name Shirley Harrison

Branch/Mail Code:

Phone Number: 202-566-1107

FAX Number:

(Signature)

(Date)

Contracting Official Name Sandra Stargarda-Lidia

Branch/Mail Code:

Phone Number: 513-487-2006

FAX Number:

(Signature)

(Date)